ENDOCYTE INC
Form 10-Q
November 08, 2018

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 001-35050

ENDOCYTE, INC.

(Exact name of Registrant as specified in its charter)

Delaware	35-1969-140
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3000 Kent Avenue, Suite A1-100

West Lafayette, IN 47906

(Address of Registrant’s principal executive offices)

Registrant’s telephone number, including area code: (765) 463-7175

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares of the registrant’s Common Stock, $0.001 par value, outstanding on October 26, 2018: 82,088,638

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

ENDOCYTE, INC.

CONDENSED BALANCE SHEETS

	December 31, 2017	September 30, 2018 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 18,559,130	$ 67,268,340
Short-term investments	78,912,297	276,942,151
Receivables	273,044	48,164
Prepaid expenses	751,255	1,552,085
Other assets	77,077	5,500,614
Total current assets	98,572,803	351,311,354
Property and equipment, net	2,182,399	1,556,314
Other noncurrent assets	7,067	2,336,637
Total assets	$ 100,762,269	$ 355,204,305
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 376,394	$ 1,095,064
Accrued wages and benefits	2,533,133	2,884,474
Accrued clinical trial expenses	689,985	1,512,346
Accrued expenses and other liabilities	946,668	2,182,883
Total current liabilities	4,546,180	7,674,767
Deferred revenue, net of current portion	731,944	332,945
Total liabilities	5,278,124	8,007,712
Stockholders' equity:		
Common stock: $0.001 par value, 100,000,000 shares authorized; 48,203,529 and 81,323,300 shares issued and outstanding at December 31, 2017 and September 30, 2018	48,204	81,323
Additional paid-in capital	404,454,909	688,527,897
Accumulated other comprehensive loss	(64,433)	(22,684)
Retained deficit	(308,954,535)	(341,389,943)
Total stockholders' equity	95,484,145	347,196,593
Total liabilities and stockholders' equity	$ 100,762,269	$ 355,204,305

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017 (unaudited)	2018	2017 (unaudited)	2018
Revenue:				
Collaboration revenue	$ 32,500	$ 85,855	$ 57,500	$ 116,175
Total revenue	32,500	85,855	57,500	116,175
Operating expenses:				
Research and development	4,089,677	8,856,028	20,739,170	21,735,588
General and administrative	3,011,176	4,788,918	10,061,722	13,198,445
Acquired in-process research and development	16,493,132	—	16,493,132	—
Total operating expenses	23,593,985	13,644,946	47,294,024	34,934,033
Loss from operations	(23,561,485)	(13,559,091)	(47,236,524)	(34,817,858)
Other income (expense), net:				
Interest income, net	264,932	959,092	734,065	2,092,397
Other income (expense), net	29,735	(7,526)	2,328	(49,353)
Net loss	(23,266,818)	(12,607,525)	(46,500,131)	(32,774,814)
Net loss per share – basic and diluted	$ (0.55)	$ (0.17)	$ (1.09)	$ (0.50)
Items included in other comprehensive income:				
Unrealized gain on available-for-sale securities	30,303	11,640	36,636	41,749
Other comprehensive income	30,303	11,640	36,636	41,749
Comprehensive loss	$ (23,236,515)	$ (12,595,885)	$ (46,463,495)	$ (32,733,065)
Weighted-average number of common shares used in net loss per share calculation – basic and diluted	42,636,567	72,043,113	42,525,693	65,648,006

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

(unaudited)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive Income	Retained	
	Shares	Amount	Capital	(Loss)	Deficit	Total
Balances December 31, 2017	48,203,529	$ 48,204	$ 404,454,909	$ (64,433)	$ (308,954,535)	$ 95,484,145
Cumulative effect of adoption of ASC 606 (See Note 3)	—	—	—	—	339,406	339,406
Balances at January 1, 2018	48,203,529	$ 48,204	$ 404,454,909	$ (64,433)	$ (308,615,129)	$ 95,823,551
Exercise of stock options	1,516,796	1,517	9,837,268	—	—	9,838,785
Issuance of common stock in connection with equity offerings	31,414,093	31,414	269,794,204	—	—	269,825,618
Stock-based compensation	163,530	163	4,346,471	—	—	4,346,634
Employee stock purchase plan	25,352	25	95,045	—	—	95,070
Net loss	—	—	—	—	(32,774,814)	(32,774,814)
Unrealized gain on securities	—	—	—	41,749	—	41,749
Balances September 30, 2018	81,323,300	$ 81,323	$ 688,527,897	$ (22,684)	$ (341,389,943)	$ 347,196,593

See accompanying notes.

ENDOCYTE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

	Nine Months Ended September 30,	
	2017	2018
	(unaudited)	
Operating activities		
Net loss	$ (46,500,131)	$ (32,774,814)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	701,133	597,557
Stock-based compensation	2,680,873	4,451,096
Acquired in-process research and development	16,493,132	—
Loss (gain) on disposal of property and equipment	114,042	(6,029)
Accretion of bond premium (discount)	1,399	(1,282,175)
Change in operating assets and liabilities:		
Receivables	157,805	224,880
Prepaid expenses and other assets	770,892	(8,398,316)
Accounts payable	(1,160,801)	557,027
Accrued wages, benefits and other liabilities	(633,288)	2,391,338
Deferred revenue	(37,500)	(47,565)
Net cash used in operating activities	(27,412,444)	(34,287,001)
Investing activities		
Purchases of property and equipment	(46,833)	(43,094)
Proceeds from disposal of property and equipment	—	90,161
Purchases of investments	(51,318,003)	(308,005,868)
Purchase of acquired in-process research and development	(12,322,349)	—
Proceeds from sale and maturities of investments	102,430,000	111,300,000
Net cash provided by (used in) investing activities	38,742,815	(196,658,801)
Financing activities		
Stock repurchase	(94,627)	(104,461)
Proceeds from exercise of warrant to purchase common stock	4,556,420	—
Proceeds from issuance of common stock in connection with equity offerings	—	269,825,618
Proceeds from the exercise of stock options	109,742	9,838,785
Proceeds from stock purchases under employee stock purchase plan	48,407	95,070
Net cash provided by financing activities	4,619,942	279,655,012
Net increase in cash and cash equivalents	15,950,313	48,709,210
Cash and cash equivalents at beginning of period	31,228,192	18,559,130
Cash and cash equivalents at end of period	$ 47,178,505	$ 67,268,340

See accompanying notes.

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ENDOCYTE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Nature of Business and Organization

Endocyte, Inc. (the "Company") is a biopharmaceutical company and leader in developing targeted therapies for the treatment of cancer. The Company uses drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. The agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate specific membrane antigen ("PSMA") in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment.

On October 17, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Novartis AG ("Novartis") and Edinburgh Merger Corporation, a wholly owned subsidiary of Novartis ("Merger Sub"), subject to the terms and conditions of which the Company will be acquired by Novartis for $24.00 per share in cash through the merger of Merger Sub with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of Novartis (the "Merger"). The consummation of the Merger is subject to certain closing conditions, including the requisite approval of our stockholders and the receipt of certain antitrust and regulatory approvals. See Note 13 – Subsequent Event of the Notes to Condensed Financial Statements contained herein for additional information regarding the Merger, and see "Risk Factors" in Part II, Item 1A herein for important information regarding certain risks associated with the Merger Agreement and the Merger.

In September 2017, the Company entered into a Development and License Agreement (the "License Agreement") with ABX advanced biochemical compounds – Biomedizinische Forschungsreagenzien GmbH ("ABX"), pursuant to which the Company acquired exclusive worldwide rights to develop and commercialize PSMA-617 agents, including the product candidate known as 177Lu-PSMA-617, a radioligand therapeutic ("RLT"). Following a successful End of Phase 2 meeting with the U.S. Food and Drug Administration (the "FDA"), in early 2018, the Company finalized the initial phase 3 VISION trial design and registration plan for 177Lu-PSMA-617.

In the three months ended June 30, 2018, the Company initiated enrollment of the VISION trial, an international, prospective, open-label, multicenter, randomized phase 3 study of 177Lu-PSMA-617 enrolling up to 750 patients with progressive PSMA-positive metastatic castration-resistant prostate cancer ("mCRPC"). 177Lu-PSMA-617 utilizes a high affinity targeting ligand to direct potent radiotherapy to prostate cancer cells. The specific targeting of this therapy comes from the "ligand" portion of the RLT, which is a small molecule designed to bind to PSMA, a protein highly expressed on the cell surface of most prostate cancer cells but absent on most normal cells. The PSMA targeting ligand in 177Lu-PSMA-617 is chemically attached to a therapeutic radioactive atom called Lutetium-177 (177Lu), which releases an energetic beta particle designed to precisely deliver cell-killing radiation to the site of

disease. Unlike traditional external beam radiotherapy, 177Lu-PSMA-617, which is administered as a systemic injection, has been designed to directly target multiple sites of PSMA-positive prostate cancer throughout the body, including the bone and soft tissue, while bypassing the PSMA-negative cells. Prior to treatment with 177Lu-PSMA-617, the patient's expression of PSMA can be determined using imaging technology, allowing for personalization of treatment so that the optimum course of therapy might be selected. As highlighted in roughly 20 peer reviewed publications of trials in the post-chemotherapy compassionate use setting, 177Lu-PSMA-617 demonstrated a prostate-specific antigen (“PSA”) response (defined as greater than 50% decline from baseline) in 40% to 60% of patients, and a Response Evaluation Criteria in Solid Tumors (“RECIST”) response rate in soft tissue disease of between 40% and 50%.

On September 10, 2018, the Company announced that, following a meeting with the FDA, it was determined that radiographic progression free survival (“rPFS”) is an appropriate efficacy endpoint in the ongoing phase 3 VISION trial to support the submission of a New Drug Application (“NDA”) for full FDA approval of 177Lu-PSMA-617 for the treatment of mCRPC. The updated trial protocol will reflect this determination on rPFS while retaining the final, fully powered overall survival (“OS”) analysis.

Under the updated VISION trial design, the two interim assessments previously planned at 50% and 70% of OS events will be replaced with a single assessment of rPFS. This assessment is expected to occur at approximately the same time that the first interim OS assessment would have occurred under the prior trial design and shortly after the time the trial is fully enrolled. If 177Lu-PSMA-617 meets the primary endpoint in the rPFS assessment, no unexpected safety issues arise, and it demonstrates no detriment in OS relative to the control arm, the Company intends to submit an NDA to seek full approval in the United States. The rPFS analysis will include approximately 450 rPFS events. Regardless of the outcome of the rPFS assessment, the Company intends to continue to follow patients in the VISION trial in order to assess the final OS alternative primary endpoint. An efficacy analysis of OS will be conducted at approximately 490 events. Other aspects of the VISION trial design, including patient treatment and assessments, study size, overall duration, and follow up remain unchanged. Secondary endpoints include RECIST response and time to first symptomatic skeletal event.

2. Significant Accounting Policies

Basis of Presentation

The accompanying condensed financial statements are prepared in conformity with U.S. generally accepted accounting principles (“GAAP”) for interim financial information to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the accompanying condensed financial statements have been included. Interim results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other future period. These condensed financial statements should be read in conjunction with the Company’s audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017. Subsequent events have been evaluated through the date of issuance, which is the same as the date this Form 10-Q is filed with the Securities and Exchange Commission (the “SEC”).

Segment Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. All long-lived assets are held in the U.S. The Company views its operations and manages its business in one operating segment.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual amounts may differ from those estimates.

Cash and Cash Equivalents

The Company considers cash and all highly liquid investments with a maturity of three months or less at the date of purchase to be cash equivalents. Cash equivalents consist primarily of money market instruments, U.S. government treasury obligations, U.S. government agency obligations, corporate obligations and repurchase agreements that are maintained by an investment manager.

Investments

Investments consist primarily of investments in U.S. Treasuries and corporate debt securities, which could also include commercial paper, that are maintained by an investment manager. Management determines the appropriate classification of marketable securities at the time of purchase and reevaluates such classification as of each balance sheet date. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss). Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities are included in other income (expense). The Company considers and accounts for other-than-temporary impairments according to the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, Investments — Debt and Equity Securities ("ASC 320"). The cost of securities sold is based on the specific-identification method. Discounts and premiums on debt securities are amortized to interest income and expensed over the term of the security.

Revenue Recognition

Commencing with reporting periods beginning January 1, 2018, the Company recognizes revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers. The Company's contract revenues consist of revenues from license and collaboration agreements. License and collaboration revenue is primarily generated through agreements with strategic partners for the development and potential commercialization of our product candidates. The terms of the agreement typically include non-refundable upfront fees, funding of research and development activities, payments based upon achievement of milestones and potential royalties on net product sales. Non-refundable upfront fees and funding of research and development activities are considered fixed consideration, while milestone payments and royalties are identified as variable consideration.

The Company recognizes revenues from license and collaboration agreements to depict the transfer of promised goods or services in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. In order to determine the appropriate amount of revenue to be recognized as the Company fulfills its obligations under a contract, the Company follows the following steps for in-scope transactions: 1) identification of the contract with a customer, 2) identification of the separate performance obligations in the contract, 3) determination of the transaction price, 4) allocation of the transaction price to the separate performance obligations in the contract, and 5) recognition of revenue when or as the Company satisfies a performance obligation.

The Company's performance obligations may include license rights, research and development services, services associated with regulatory submission and approval processes and services related to potential commercialization processes. Significant judgment may be required to determine the level of effort required under an arrangement and the period over which the Company expects to satisfy its performance obligations under the arrangement. If the Company cannot reasonably estimate when its performance obligations either are satisfied or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method.

License Agreements

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that may be bundled with other promises, the Company will utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. Because the drug development process is lengthy and the Company's collaboration agreements typically cover activities over several years, this approach may result in the deferral of significant amounts of revenue into future periods. Each reporting period, the Company evaluates the measure of progress and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by the Company) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received. When the Company's assessment of probability of achievement changes and variable consideration becomes probable, any additional estimated consideration is allocated to each performance obligation based on the estimated relative standalone selling prices of the promised good or service underlying each performance obligation and recorded in license, collaboration, and other revenues based upon when the customer obtains control of each element.

Royalty Payments

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied. To date, none of the Company's products have been approved and therefore the Company has not earned any royalty revenue from product sales.

Research and Development Expenses

Research and development expenses represent costs associated with the ongoing development of novel therapeutics and companion imaging agents for personalized targeted therapies and include salaries and employee benefits, supplies, facility costs related to research activities, and expenses for clinical trials. The Company records accruals for clinical trial expenses based on the estimated amount of work completed. The Company monitors patient enrollment levels and related activities to the extent possible through internal reviews, correspondence, and discussions with research organizations. In the event that a clinical trial is terminated early, the Company records, in the period of termination, an accrual for the estimated remaining costs to complete and close out the trial pursuant to ASC Topic 420, Exit or Disposal Cost Obligations, as a terminated trial does not provide any future economic benefit to the Company. See Note 11 – Restructuring Costs of the Notes to Condensed Financial Statements contained herein for amounts paid during the three and nine months ended September 30, 2018 related to the Company's restructuring activities.

Upfront payments made in connection with business collaborations and research and development arrangements are evaluated under ASC Subtopic 730-20, Research and Development Arrangements. Amounts related to future research

and development, including clinical drug supply, are capitalized as prepaid research and development and are expensed over the service period based upon the level of services provided. As of September 30, 2018, the Company had approximately $7.8 million of capitalized research and development costs included in prepaid expenses, other assets and other noncurrent assets.

Acquired In-Process Research and Development Expense

The Company has acquired and may continue to acquire the rights to develop and commercialize new drug candidates. In accordance with ASC Subtopic 730-25, Accounting for Research and Development Costs, the upfront payments to acquire a new drug compound, as well as future milestone payments when paid or payable, are immediately expensed as acquired in-process research and development ("IPR&D") in transactions other than a business combination provided that the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no alternative future use. Upon obtaining regulatory approval for marketing, any related milestone payments may be capitalized and amortized over the life of the asset.

Stock-Based Compensation

The Company accounts for its stock-based compensation pursuant to ASC Topic 718, Compensation — Stock Compensation ("ASC 718"), which requires the recognition of the fair value of stock-based compensation in net income (loss). Stock-based compensation consists of stock options, which are granted at exercise prices at or above the fair market value of the Company's common stock on the dates of grant, service-based restricted stock units ("RSUs") and

shares available for purchase under the Company's 2010 Employee Stock Purchase Plan ("ESPP"). For RSUs and stock options issued by the Company, stock-based compensation expense is recognized ratably over the service period and forfeitures are accounted for as they occur. The Company recognizes compensation cost based on the grant date fair value estimated in accordance with the provisions of ASC 718.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method and the if-converted method. For purposes of this calculation, stock options, warrants, RSUs and shares to be purchased under the ESPP are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Common stock equivalents

As of September 30, 2017 and 2018, the following number of potential common stock equivalents were outstanding:

	As of September 30,	
	2017	2018
Outstanding common stock options	6,265,333	5,309,344
Outstanding warrants	756,647	722,000
Outstanding RSUs	478,087	1,510,460
Shares to be purchased under the ESPP	18,323	11,410
Total	7,518,390	7,553,214

These common stock equivalents were excluded from the determination of diluted net loss per share in the three and nine month periods ended September 30, 2017 and 2018 due to their anti-dilutive effect on earnings. For additional information on the outstanding warrants, see Note 8 – Warrants of the Notes to Condensed Financial Statements contained herein.

3. New Accounting Pronouncements

Recently Issued Accounting Standards

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, Leases, an update to ASC Topic 842, Leases. This guidance requires lessees to recognize leases as assets and liabilities on their balance sheets but recognize expenses on their income statements in a manner similar to the current accounting guidance. For lessors, the guidance also modifies the classification criteria and the accounting for sales-type and direct finance leases. This update is effective for the Company for interim and annual reporting periods beginning January 1, 2019. The Company does not expect the adoption of this guidance to have a material impact on its financial statements.

Recently Adopted Accounting Standards

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), to clarify the principles used to recognize revenue for all entities. Under ASU 2014-09 as subsequently amended and clarified ("ASC 606"), an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In order to do so, an entity would follow the five-step process for in-scope transactions: 1) identify the contract with a customer, 2) identify the separate performance obligations in the contract, 3) determine the transaction price, 4) allocate the transaction price to the separate performance obligations in the contract, and 5) recognize revenue when (or as) the entity satisfies a performance obligation. ASC 606 was effective for the Company for interim and annual reporting periods beginning January 1, 2018. The Company adopted ASC 606 in the nine months ended September 30, 2018 using the modified retrospective method by recognizing the cumulative effect of initially applying the new revenue standard as an adjustment to the opening balance of retained deficit. The cumulative effect related to the adoption of ASC 606 was a $0.3 million decrease to the opening balance of retained deficit at January 1, 2018. The Company had deferred revenue related to its agreement with Nihon Medi-Physic Co., LTD. ("NMP") of approximately $0.4 million at September 30, 2018 and will continue to record the revenue on a straight-line basis over the remaining estimated performance obligation period of approximately six years. The Company currently has a limited number of contracts with customers and only one revenue stream, which relates to collaboration and licensing arrangements, and which represents all of the revenue earned in the three and nine months ended September 30, 2018. The adoption of ASC 606 did not have a material impact on the Company's financial statements and is not expected to have a material impact on the Company's financial statements on an ongoing basis.

4. Other Comprehensive Income

The following tables summarize the accumulated balances related to each component of other comprehensive income for the three months ended September 30, 2017 and 2018:

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at June 30, 2017	$ (34,863)	$ (34,863)
Unrealized gain	30,303	30,303
Other comprehensive income	30,303	30,303
Balance at September 30, 2017	$ (4,560)	$ (4,560)

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at June 30, 2018	$ (34,324)	$ (34,324)
Unrealized gain	11,640	11,640
Other comprehensive income	11,640	11,640
Balance at September 30, 2018	$ (22,684)	$ (22,684)

The following tables summarize the accumulated balances related to each component of other comprehensive income for the nine months ended September 30, 2017 and 2018:

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at December 31, 2016	$ (41,196)	$ (41,196)
Unrealized gain	36,636	36,636
Other comprehensive income	36,636	36,636
Balance at September 30, 2017	$ (4,560)	$ (4,560)

	Unrealized Net Gains (Losses) on Securities	Accumulated Other Comprehensive Gains (Losses)
Balance at December 31, 2017	$ (64,433)	$ (64,433)
Unrealized gain	41,749	41,749
Other comprehensive income	41,749	41,749
Balance at September 30, 2018	$ (22,684)	$ (22,684)

5. Investments

The Company applies the fair value measurement and disclosure provisions of ASC Topic 820, Fair Value Measurements and Disclosures (“ASC 820”). ASC 820, which defines fair value, establishes a framework for measuring fair value in GAAP, and expands disclosures about fair value measurements. Investments consist primarily of investments with maturities greater than three months, but no longer than 24 months, when purchased.

ASC 820 establishes a three-level valuation hierarchy for fair value measurements. These valuation techniques are based upon the transparency of inputs (observable and unobservable) to the valuation of an asset or liability as of the measurement date. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 — Valuation is based on quoted prices for identical assets or liabilities in active markets.

Level 2 — Valuation is based on quoted prices for similar assets or liabilities in active markets, or other inputs that are observable for the asset or liability, either directly or indirectly, for the full term of the financial instrument.

Level 3 — Valuation is based upon other unobservable inputs that are significant to the fair value measurement.

The fair value of the Company's fixed income securities is based on a market approach using quoted market values.

The following table summarizes the fair value of cash and cash equivalents and investments as of December 31, 2017:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$ 2,544,972	$ 2,544,972	$ —	$ 2,544,972
Cash equivalents (maturity of 3 months or less)				
Repurchase agreements	10,000,000	—	10,000,000	10,000,000
Money market funds	6,014,158	6,014,158	—	6,014,158
Cash and cash equivalents	$ 18,559,130	$ 8,559,130	$ 10,000,000	$ 18,559,130
Short-term investments (due within 1 year)				
U.S. government treasury obligations	$ 63,034,548	$ 62,970,115	$ —	$ 62,970,115
Corporate obligations	15,942,182	—	15,942,182	15,942,182
Total short-term investments	$ 78,976,730	$ 62,970,115	$ 15,942,182	$ 78,912,297

The following table summarizes the fair value of cash and cash equivalents and investments as of September 30, 2018:

Description	Cost	Level 1	Level 2	Fair Value (Carrying Value)
Cash				
Cash	$ 7,280,004	$ 7,280,004	$ —	$ 7,280,004
Cash equivalents (maturity of 3 months or less)				
Repurchase agreements	10,000,000	—	10,000,000	10,000,000
Money market funds	35,004,236	35,004,236	—	35,004,236
U.S. government agency obligations	14,984,175	—	14,984,100	14,984,100
Cash and cash equivalents	$ 67,268,415	$ 42,284,240	$ 24,984,100	$ 67,268,340
Short-term investments (due within 1 year)				
U.S. government treasury obligations	$ 187,315,613	$ 187,297,850	$ —	$ 187,297,850
Corporate obligations	89,649,086	—	89,644,301	89,644,301
Total short-term investments	$ 276,964,699	$ 187,297,850	$ 89,644,301	$ 276,942,151

All securities held at December 31, 2017 and September 30, 2018, were classified as available-for-sale as defined by ASC 320.

Total unrealized gross gains were $2,464 at September 30, 2018. There were no unrealized gross gains as of December 31, 2017. Total unrealized gross losses were $64,433 and $25,148 as of December 31, 2017 and September 30, 2018, respectively. The Company does not consider any of the unrealized losses to be other-than-temporary impairments because the Company has the intent and ability to hold investments until they recover in value. There were no total realized gross gains or total realized gross losses for the three or nine months ended September 30, 2017 and 2018.

6. Collaboration and Other Arrangements

Isotope Technologies Garching GmbH Global Supply Agreement

In July 2018, the Company entered into a Global Supply Agreement (the "Supply Agreement") with ITG Isotope Technologies Garching GmbH ("ITG"). The Supply Agreement supersedes the clinical supply agreement for the same product that the Company announced on February 26, 2018. Under the Supply Agreement, ITG agrees to supply the Company with, and the Company agrees to purchase, 100% of the no-carrier-added lutetium-177 (the "Product"), which is the therapeutic radioactive atom portion of 177Lu-PSMA-617, required for the Company's phase 3 VISION trial. The Company also agrees to purchase, and ITG agrees to supply, at least 50%, and up to 100% at the Company's request, of the Company's Product needs for 177Lu-PSMA-617 during the commercial phase, which begins upon the first commercial country launch of 177Lu-PSMA-617 following receipt of a full marketing authorization allowing sale of such product in that first country.

The Supply Agreement also sets forth various terms relating to the manufacture, ordering, supply and payment regarding the Product. The Supply Agreement also includes provisions relating to, among others, delivery, inspection procedures, warranties, quality management, compliance, forecasts, intellectual property rights, indemnification, and confidentiality.

The initial term of the Supply Agreement continues until December 31, 2035, subject to earlier termination as described below. After the initial term, the Supply Agreement will automatically be extended for successive periods of two years each unless either party terminates the Supply Agreement by giving prior written notice. Either party may terminate the Supply Agreement for cause if the other party: (i) becomes insolvent or has a receiver or liquidator appointed or enters into a composition or bankruptcy with its creditors; (ii) materially breaches its material obligations under the Supply Agreement and fails to commence to cure such breach within a specified time following receiving notice of breach; (iii) fails to pay any insurance premium or any amount under the Supply Agreement when due and fails to cure such breach within a specified time after becoming aware of such failure to pay; or (iv) fails to perform its obligations under the Supply Agreement by reason of Force Majeure for more than a specified time period. In addition, the Supply Agreement contains other termination provisions that may apply if certain restrictive conditions are met.

In August 2018, the Company paid ITG a one-time, non-refundable upfront payment under the Supply Agreement, which was $5.8 million. Under ASC Subtopic 730-20, Research and Development Arrangements, the Company capitalized the payment as other current and noncurrent assets and will be recognizing the expense over the service period, which is considered to be delivery of the Product, during the phase 3 VISION trial. The balance of other current and noncurrent assets related to the upfront payment under the Supply Agreement as of September 30, 2018 was $5.3 million and $0.5 million, respectively.

ABX Development and License Agreement

In September 2017, the Company entered into the License Agreement with ABX that grants the Company exclusive worldwide rights to develop and commercialize PSMA-617 agents. Under the terms of the License Agreement, the Company will be responsible for, and bear the future costs of, worldwide development and commercialization of PSMA-617. As consideration for the exclusive license, the Company made an upfront cash payment on September 29, 2017 of approximately $11.9 million to ABX, consisting of $12.0 million less an immaterial expense reimbursement amount, and issued to ABX 2,000,000 shares of the Company's common stock (see Note 7 – Stockholders' Equity (Deficit) of the Notes to Condensed Financial Statements for additional information regarding this issuance) and two warrants to purchase, in the aggregate, 4,000,000 shares of the Company's common stock (see Note 8 – Warrants of the Notes to Condensed Financial Statements for additional information regarding the warrants). The License Agreement also obligates the Company to pay ABX regulatory milestone payments of up to $25.0 million, sales milestone payments of up to $135.0 million, and tiered royalties, beginning in the mid-teens and not to exceed the mid-twenties, based on percentages of net sales.

In addition, under a three-party agreement, entered into in October 2017, among the Company, the University of Sydney (the "University") and ANZUP, a cooperative cancer trials group operating in Australia and New Zealand pursuing research in genito-urinary malignancies, ANZUP sponsors jointly with the University a randomized phase 2 multi-center TheraP trial of 177Lu-PSMA-617 versus cabazitaxel in 200 mCRPC patients. The TheraP trial commenced enrollment in the first quarter of 2018. Under the three-party agreement, the Company provides product and financial support for the trial. The Company will have access to data generated from the trial, which is a potentially important supportive trial for future regulatory submissions. The primary financial obligations of the trial, along with labeling PSMA-617 with Lutetium-177, will be the responsibility of the University and ANZUP.

NMP License and Commercialization Agreement

In August 2013, the Company entered into a license and commercialization agreement with NMP that grants NMP the right to develop and commercialize etarfolatide in Japan for use in connection with any folate receptor-targeted therapeutic drug in Japan. The Company received a $1.0 million non-refundable upfront payment, is eligible for up to $4.5 million based on the successful achievement of regulatory goals for etarfolatide in five different cancer indications and is eligible to receive double-digit percentage royalties on sales of etarfolatide in Japan.

For revenue recognition purposes, the Company historically viewed the agreement with NMP as a multiple element arrangement upon execution of the agreement in 2013. The Company's deliverables were accounted for as a single unit of account, therefore the non-refundable upfront payment was being recognized on a straight-line basis over the performance period which had been determined to continue through the estimated termination date of the contract, or through the end of 2033. In the nine months ended September 30, 2018, the Company adopted ASC 606 and therefore

analyzed the agreement with NMP using the five-step process as described in Note 3 – New Accounting Pronouncements of the Notes to Condensed Financial Statements contained herein. The Company determined that the upfront payment of $1.0 million relates to one performance obligation, which was determined to be the successful development and commercialization of etarfolatide in connection with a related folate receptor-targeted therapeutic drug in Japan, and should be allocated over the performance period that the Company estimates will be required to satisfy the combined performance obligation rather than the period over which the final undelivered item was estimated to be delivered, which was the life of the contract, under the previous standard. Under the modified retrospective method of adoption of ASC 606, the Company recorded a cumulative effect adjustment to reduce deferred revenue by $0.3 million and to decrease its retained deficit at January 1, 2018. The Company had deferred revenue related to the agreement with NMP of approximately $0.4 million at September 30, 2018 and will continue to record the revenue on a straight-line basis over the remaining estimated performance obligation period of approximately six years. The adoption of ASC 606 did not have a material effect on the Company’s financial statements.

The arrangement with NMP includes milestone payments of up to approximately $4.5 million and the milestones are based on the commencement of clinical trials in Japan for specific and non-specific indications and filing for approval in Japan for specific and non-specific indications. The Company evaluated each of these milestone payments and believes that all of the milestones should be excluded from the transaction price due to substantial performance risk. In order for the milestones to be reached, the Company must complete additional clinical trials which show a positive outcome or receive approval from a regulatory authority. To date, the products have not been approved in Japan and no revenue has been recognized related to the regulatory milestones or royalties.

NMP has the right to terminate the collaboration agreement on 90 days notice prior to the first commercial sale in Japan and six months notice after the first commercial sale in Japan. NMP also has the right to terminate the agreement on six months notice if the Company fails to launch any folate receptor-targeted therapeutic drug after receiving regulatory approval in Japan. NMP and the Company each have the right to terminate the agreement due to the material breach or insolvency of the other party. Upon termination of the agreement depending on the circumstances, the parties have varying rights and obligations with respect to licensing and related regulatory materials and data.

7. Stockholders’ Equity (Deficit)

Public Offerings of Common Stock

On September 14, 2018, the Company closed an underwritten registered public offering of 10,878,379 shares of its common stock, which included the underwriters’ exercise in full of their option to purchase additional shares. The shares were sold at a public offering price of $18.50 per share. In the nine months ended September 30, 2018, the Company received aggregate net proceeds from this offering of approximately $188.9 million, after deducting underwriting discounts and commissions of $12.1 million and offering expenses paid by the Company of $0.3 million.

On March 2, 2018, the Company closed an underwritten registered public offering of 20,535,714 shares of its common stock, which included the underwriters’ exercise in full of their option to purchase additional shares. The shares were sold at a public offering price of $4.20 per share. In the nine months ended September 30, 2018, the Company received aggregate net proceeds from this offering of approximately $80.9 million, after deducting underwriting discounts and commissions of $5.2 million and offering expenses paid by the Company of $0.1 million.

Issuances Related to the License Agreement

In connection with the License Agreement, the Company issued to ABX on September 29, 2017, 2,000,000 unregistered shares of the Company's common stock and two warrants to purchase up to 4,000,000 shares of the Company's common stock. Pursuant to a Registration Rights Agreement entered into with ABX, the Company registered for resale these 6,000,000 shares of the Company's common stock with the SEC on a Form S-3 Registration Statement that was declared effective on October 24, 2017. One of the warrants to purchase 3,278,000 shares of the Company's common stock was exercised on September 29, 2017, resulting in one outstanding warrant to purchase 722,000 shares of the Company's common stock being outstanding on September 30, 2018. On October 19, 2018 the remaining outstanding warrant was exercised in part, with respect to 280,000 shares of the Company's common stock, resulting in 442,000 shares of the Company's common stock remaining subject to issuance under the outstanding warrant. See Note 8 – Warrants of the Notes to Condensed Financial Statements contained herein for additional information.

Stock-Based Compensation Plans

The Company had equity awards outstanding under two stock-based compensation plans at September 30, 2018. The awards made under the plan adopted in 2007 consisted of stock options. The 2010 Equity Incentive Plan (the "2010 Plan"), which is the only plan under which awards may currently be made, authorizes awards in the form of stock options, stock appreciation rights, restricted stock, RSUs, performance-based RSUs and performance units and performance shares. Awards under the 2010 Plan may be made to employees, directors and certain consultants as determined by the compensation committee of the board of directors. There were 11,850,563 and 13,296,563 shares of common stock authorized and reserved under these plans at December 31, 2017 and September 30, 2018, respectively.

Stock Options

Under the various plans, employees have been granted both incentive and non-qualified stock options, while directors and consultants have been granted non-qualified options. The plans allow the holder of an option to purchase common stock at the exercise price, which was at or above the fair value of the Company's common stock on the date of grant.

Generally, options granted under the 2007 plan in connection with an employee's commencement of employment vested over a four-year period with one-half of the shares subject to the grant vesting after two years of employment and the remaining options vesting monthly over the remainder of the four-year period. Options granted under the 2007 plan for performance or promotions vested monthly over a four-year period. Generally, options granted under the 2010 Plan vest annually over a three-year or four-year period. Unexercised stock options terminate on the tenth anniversary date after the date of grant. The Company recognizes stock-based compensation expense over the requisite service period of the individual grantees, which generally equals the vesting period. The Company utilizes a Black-Scholes option-pricing model to estimate the value of stock options. The Black-Scholes model allows the use of a range of assumptions related to historical volatility, risk-free interest rate, employee exercise behavior and dividend yield.

The Company is using the "simplified" method for "plain vanilla" options to estimate the expected term of the stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate assumption is derived from the weighted-average yield of a U.S. Treasury security with the same term as the expected life of the options, the volatility is calculated based on volatility of the Company's daily stock prices since the initial public offering over the same term as the expected life of the options and the dividend yield assumption is based on historical experience and the Company's estimate of future dividend yields.

The weighted-average value of the individual options granted during the three and nine months ended September 30, 2017 and 2018 were determined using the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2018	2017	2018
Expected volatility	0.0 %	90.6 %	92.7 %	100.4 %
Risk-free interest rate	0.00 %	2.78 %	2.15 %	2.71 %
Weighted-average expected life (in years)	0.0	6.3	6.9	6.9
Dividend yield	0.00 %	0.00 %	0.00 %	0.00 %

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The Company's stock option activity and related information are summarized as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Outstanding at January 1, 2018	5,878,660	$ 5.93		
Granted during period	688,192	3.07		
Exercised during period	(561,088)	4.10		
Expired during period	(8,993)	3.06		
Outstanding at March 31, 2018	5,996,771	$ 5.78	6.18	$ 22,125,418
Exercisable at March 31, 2018	4,290,445	$ 6.92	5.02	$ 11,551,954
Outstanding at April 1, 2018	5,996,771	5.78		
Granted during period	242,400	10.86		
Exercised during period	(512,795)	8.16		
Forfeited during period	(5,869)	2.82		
Outstanding at June 30, 2018	5,720,507	$ 5.79	6.28	$ 45,908,925
Exercisable at June 30, 2018	3,970,287	$ 6.56	5.09	$ 28,812,888
Outstanding at July 1, 2018	5,720,507	5.79		
Granted during period	48,700	16.74		
Exercised during period	(442,913)	7.57		
Forfeited during period	(16,950)	4.77		
Outstanding at September 30, 2018	5,309,344	$ 5.74	6.14	$ 63,541,222
Exercisable at September 30, 2018	3,550,137	$ 6.42	4.84	$ 40,064,166

As of September 30, 2018, the total remaining unrecognized compensation cost related to stock options granted was $4.9 million, which is expected to be recognized over a weighted average period of approximately 1.7 years.

Restricted Stock Units

RSUs are service-based awards that will vest and be paid in the form of one share of the Company's common stock for each RSU, generally in two, three or four equal annual installments beginning on the first anniversary of the date of grant of an RSU. As of September 30, 2018, the Company had 1,510,460 RSU awards outstanding. As of September 30, 2018, the total remaining unrecognized compensation cost related to RSUs was $4.6 million, which is expected to be recognized over a weighted average period of approximately 1.4 years.

The following table sets forth the number of RSUs that were granted, vested and forfeited in the periods indicated:

	Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2018	1,383,770	$ 5.05
Granted during period	301,958	3.02
Vested during period	(161,147)	4.27
Outstanding at March 31, 2018	1,524,581	$ 4.73
Outstanding at April 1, 2018	1,524,581	$ 4.73
Granted during period	56,150	12.19
Vested during period	(30,150)	2.47
Forfeited during period	(29,683)	5.35
Outstanding at June 30, 2018	1,520,898	$ 5.04
Outstanding at July 1, 2018	1,520,898	$ 5.04
Granted during period	3,000	13.60
Vested during period	(5,938)	4.85
Forfeited during period	(7,500)	5.01
Outstanding at September 30, 2018	1,510,460	$ 5.06

Employee Stock Purchase Plan

At January 1, 2018, 769,542 common shares were available for issuance under the ESPP. Shares may be issued under the ESPP twice a year. In the nine months ended September 30, 2018, plan participants purchased 25,352 shares of common stock under the ESPP at an average purchase price of $3.75 per share. At September 30, 2018, there were 744,190 common shares available for issuance under the ESPP.

8. Warrants

In connection with the License Agreement, the Company issued to ABX on September 29, 2017, two warrants to purchase up to 4,000,000 shares of the Company’s common stock, at a per share exercise price of $1.39, which was equal to the average closing price of the Company’s common stock during the 30 calendar days prior to September 29, 2017. The Company accounted for the warrants at fair value in stockholders’ equity. Immediately upon issuance, ABX assigned the warrants to an affiliate and certain related parties, which exercised a warrant for 3,278,000 shares of the Company’s common stock on September 29, 2017, resulting in proceeds to the Company in the amount of approximately $4.6 million. The remaining outstanding warrant, covering an aggregate of 722,000 shares of the Company’s common stock, remained outstanding as of September 30, 2018, is exercisable until September 29, 2027, and is subject to restrictions on transfer. This outstanding warrant was valued as of September 30, 2018 using the Black-Scholes model utilizing a ten-year term, the Company’s historic volatility of 91.1%, and an interest rate of

2.28% which is the risk-free interest rate of a treasury bond with the same term as the outstanding warrant, of which inputs are level 2 fair value measurements. There were no other outstanding warrants as of September 30, 2018.

On October 19, 2018, the remaining outstanding warrant was exercised in part, with respect to 280,000 shares of the Company’s common stock, resulting in 442,000 shares of the Company’s common stock remaining subject to issuance under that outstanding warrant. The outstanding warrant contains a conversion feature in the case of certain mergers or consolidations by the Company. Pursuant to the terms of the Merger Agreement and the terms of the outstanding warrant, if the Merger is consummated, the outstanding warrant will be deemed to be automatically exercised immediately prior to the effective time of the Merger, and the holder of the outstanding warrant will participate in the Merger as a holder of the Company’s common stock on the same terms as other holders of the Company’s common stock, but the holder’s aggregate consideration received in the Merger will be reduced by the aggregate exercise price then in effect for the shares of the Company’s common stock purchasable under the outstanding warrant.

9. Income Taxes

The Company accounts for income taxes under the liability method in accordance with the provisions of ASC Topic 740, Income Taxes. The Company recognizes future tax benefits, such as net operating losses, to the extent those benefits are expected to be realized in future periods. Due to uncertainty surrounding the realization of its deferred tax assets, the Company has recorded a valuation allowance against its net deferred tax assets. The Company experienced a change in ownership as defined under Section 382 of the U.S. Internal Revenue Code (the "Code") in August 2011. As a result, the future use of its net operating losses and credit equivalents, after giving effect to net unrealized built-in gains, was previously limited, but the limitations associated with the change in ownership in August 2011 ended as of December 31, 2017. All amounts are available for use if the Company generates future taxable income prior to expiration of the net operating losses, which will begin in 2021. The utilization of the net operating loss carryforwards could be limited beyond the Company's generation of taxable income if an additional change in the underlying ownership of the Company's common stock has occurred subsequent to August 2011, resulting in a limitation on the amounts that could be utilized in any given period under Section 382 of the Code.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "2017 Tax Act") which, among other provisions, reduced the corporate income tax rate from 35% to 21% effective January 1, 2018. During the fourth quarter of 2017, the Company revalued its net deferred tax assets using the newly enacted rate, resulting in a reduction of its net deferred tax assets of $33.1 million. The Company also reduced its valuation allowance by $33.1 million, resulting in no income tax expense being recognized as a result of the revaluation. The Company's estimate of the impacts of the 2017 Tax Act are provisional and are based upon its analysis and interpretations of currently available information. Uncertainties remain regarding the impact of the 2017 Tax Act due to future regulatory and rulemaking processes, prospects of additional corrective or supplemental legislation, and potential trade or other litigation. These uncertainties, along with the Company's completion of the calculations and potential changes in its initial assumptions as new information becomes available, could cause the actual charge to ultimately differ from the provisional amount recorded in 2017 related to the enactment of the 2017 Tax Act. All provisional amounts recorded by the Company are fully reserved. There were no adjustments in the nine months ended September 30, 2018 to the provisional amount recorded in the fourth quarter of 2017.

10. Commitments and Contingencies

On November 6, 2018, a lawsuit captioned Elaine Wang v. Endocyte, Inc., et al., Civil Action No. 4:18-cv-00085, was filed by a purported stockholder of the Company in the United States District Court, Northern District of Indiana, against the Company and the members of the Company's Board of Directors. The complaint alleges, among other things, that the preliminary proxy statement filed by the Company with the SEC on October 31, 2018 related to the special meeting of the Company's stockholders to be held in connection with the Merger, contained untrue statements of fact and/or omitted material facts necessary to make the statements made in such preliminary proxy statement not misleading, and that therefore the Company and the members of the Company's Board of Directors violated Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-9 thereunder. The lawsuit further alleges that the members of the Company's Board of Directors violated Section 20(a) of the Exchange Act. The lawsuit seeks, among other things, injunctive relief: (i) enjoining the consummation of the Merger unless and

until material information that was allegedly omitted from the Company's preliminary proxy statement is disclosed; (ii) rescinding, to the extent already implemented, the Merger Agreement or any of the terms thereof, or granting plaintiff rescissory damages; and (iii) awarding plaintiff the costs and disbursements of the action, including reasonable attorneys' and expert fees and expenses. The Company and the members of the Company's Board of Directors believe the lawsuit is without merit and intend to vigorously defend against it.

11. Restructuring Costs

In June 2017, the Company refocused its clinical development efforts and aligned its resources to focus on the Company's highest value opportunities while maintaining key capabilities. The Company's restructuring activities included a reduction of its workforce by approximately 40%, as well as stopping enrollment in its EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. In December 2017, the Company stopped enrollment in its EC1456 ovarian cancer surgical trial. Pursuant to ASC Topic 420, Exit or Disposal Cost Obligations, the Company recorded $2.3 million of restructuring expenses in the nine months ended September 30, 2017 as follows:

- included in research and development expenses were expenses for employee termination benefits of $0.9 million, $0.9 million for the remaining EC1456 phase 1b trial expenses, including site close-out expenses, $0.3 million related to other restructuring expenses, and $0.1 million related to fixed asset impairment charges; and

- included in general and administrative expenses were expenses for employee termination benefits of $0.1 million.

As of June 30, 2018, the Company had paid all severance and other costs related to the restructuring activities.

At December 31, 2017, the Company had a clinical trial accrual balance related to the EC1456 phase 1b trial termination of $106,900. There were no material adjustments to the EC1456 phase 1b trial termination accrual balance during the three and nine months ended September 30, 2018, and payments made against the accrual in those periods were $14,800 and $106,900, respectively. As of September 30, 2018, there was no remaining accrual balance related to the restructuring activities and all payments had been made.

12. Related Party

BlinkBio Clinical Supply and License Option Agreement

In August 2018, the Company entered into a Clinical Supply and License Option Agreement (the “BlinkBio Agreement”) with BlinkBio to provide a clinical supply of etarfolatide, the Company’s imaging agent that targets the folate receptor, for use in a phase 1 clinical trial and regulatory, clinical and manufacturing consulting support, as well as an option to enter into an exclusive license to use etarfolatide. Colin Goddard, who is the Chairman and Chief Executive Officer and a significant stockholder of BlinkBio, currently serves as a member of the Company’s Board of Directors. The BlinkBio Agreement provides for BlinkBio to pay the Company an annual fee of $50,000, payable beginning on the effective date of the BlinkBio Agreement and each year thereafter on the anniversary of the effective date, for the Company’s consulting support under the BlinkBio Agreement. The BlinkBio Agreement provides for milestone and license option amounts to be payable by BlinkBio to the Company upon certain occurrences, as well as for BlinkBio to reimburse the Company for certain costs. The Company received the nonrefundable, annual fee of $50,000 from BlinkBio in the three months ended September 30, 2018. The Company has determined that the deliverables under the BlinkBio Agreement meet the criteria required for separate performance units for the purposes of revenue recognition, and as a result, the Company recognized revenue from the nonrefundable, annual fee when the performance obligation of delivering certain consultation services had been achieved and there was reasonable assurance of collectability.

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13. Subsequent Event

On October 17, 2018, the Company entered into the Merger Agreement with Novartis and Merger Sub. Subject to the terms and conditions of the Merger Agreement, Merger Sub will be merged with and into the Company, with the Company continuing as the surviving corporation and a wholly-owned subsidiary of Novartis.

Pursuant to the Merger Agreement, at the effective time of the Merger (the “Effective Time”), each issued and outstanding share of Company common stock, par value $0.001 per share (other than such shares owned by the Company, Novartis or Merger Sub immediately prior to the Effective Time (which shares will be canceled) and such shares with respect to which the holder thereof properly exercises appraisal rights (and does not validly withdraw, waive or otherwise lose such rights) under Delaware law), will automatically be converted into the right to receive $24.00 in cash, without interest and less any applicable withholding taxes (the “Merger Consideration”).

At the Effective Time, each Company option to purchase shares of Company common stock (a “stock option”) that is outstanding and unexercised immediately prior to the Effective Time, whether vested or unvested, will (i) if the exercise price of such stock option is less than the Merger Consideration, be canceled, with the holder of such stock option becoming entitled to receive an amount in cash, without interest, equal to (a) the excess of the Merger Consideration over the exercise price of the stock option, multiplied by (b) the number of shares of Company common stock subject to such stock option as of immediately prior to the Effective Time (subject to any applicable withholding taxes); or (ii) if the exercise price of such stock option is equal to or greater than the Merger Consideration, be canceled without any consideration being payable.

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Also at the Effective Time, each restricted stock unit of the Company ("RSU") that is outstanding and not settled immediately prior to the Effective Time, whether vested or unvested, will be canceled and converted into the right to receive an amount in cash, without interest, equal to the Merger Consideration multiplied by the number of shares of Company common stock subject to such RSU as of immediately prior to the Effective Time (subject to any applicable withholding taxes).

The consummation of the Merger is subject to certain closing conditions, including (i) the adoption of the Merger Agreement by the holders of a majority of the outstanding shares of Company common stock (the "Stockholder Approval"), (ii) the expiration or termination of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and under Section 721 of the Defense Production Act of 1950, as amended, (iii) the receipt of certain other required regulatory approvals, if such approvals are required to complete the merger, and (iv) the absence of any legal restraints that have the effect of preventing the consummation of the Merger. Moreover, each party's obligation to consummate the Merger is subject to certain other conditions, including the accuracy of the other party's representations and warranties in the Merger Agreement (subject to certain materiality qualifiers) and the other party's compliance in all material respects with its obligations under the Merger Agreement. In addition, Novartis' and Merger Sub's obligation to consummate the Merger is subject to the absence of a Company Material Adverse Effect (as defined in the Merger Agreement). Consummation of the Merger is not subject to a financing condition.

The Merger Agreement contains customary representations and warranties of each of the Company, Novartis and Merger Sub relating to their respective businesses and certain matters related to the Merger Agreement. The Merger Agreement contains certain covenants, including covenants providing (i) for each of the parties to use reasonable best efforts to cause the transactions under the Merger Agreement to be consummated, (ii) for the Company to carry on its business in the ordinary course consistent with past practice during the interim period between the execution of the Merger Agreement and completion of the Merger and (iii) for the Company not to engage in certain kinds of transactions during that period.

The Merger Agreement obliges the Company to abide by customary "no-shop" restrictions on its ability to solicit alternative takeover proposals from third parties and to provide non-public information to and enter into discussions or negotiations with third parties regarding alternative takeover proposals. Notwithstanding this obligation, prior to the receipt of the Stockholder Approval, if the Company receives an unsolicited alternative takeover proposal that the Company's Board of Directors determines in good faith (after consultation with the Company's legal counsel and financial advisor) constitutes, or would reasonably be expected to lead to, a Superior Proposal (as defined in the Merger Agreement and summarized below) and that the failure to take such action would be inconsistent with its fiduciary duties under applicable law, the Company may under certain circumstances furnish information to and engage in discussions or negotiations with the third party making such alternative takeover proposal. A "Superior Proposal" generally is any bona fide written takeover proposal to acquire at least a majority of the outstanding shares of Company common stock or of the assets of the Company, which proposal, in the good faith determination of the Company's Board of Directors (after consultation with the Company's legal counsel and financial advisor), (i) is more favorable from a financial point of view to the Company's stockholders than the transactions under the Merger Agreement, taking into account changes to the Merger Agreement proposed by Novartis in response thereto, and (ii) is reasonably capable of being completed, taking into account all aspects of such proposal. Prior to the Company entering into a written definitive agreement for, or effecting a change in recommendation of the Company's Board of

Directors in connection with, a Superior Proposal, the Company must provide Novartis with advance written notice of its intention to do so and Novartis will generally have at least four business days after receipt of such notice to negotiate with the Company to make such adjustments in the terms and conditions of the Merger Agreement as would permit the Company's Board of Directors not to enter into such a definitive agreement or change its recommendation.

The Merger Agreement contains certain customary termination rights for the Company and Novartis, including a right to terminate the Merger Agreement if the Merger is not completed by July 17, 2019, (as such date may be extended to April 17, 2020 pursuant to the terms of the Merger Agreement, the "Outside Date"). The Merger Agreement further provides that, upon termination of the Merger Agreement under certain specified circumstances, including, among others, the Company's termination of the Merger Agreement to enter into a written definitive agreement for a Superior Proposal or following a change in recommendation of the Company's Board of Directors, the Company will be obligated to pay Novartis a termination fee of $73.5 million. If the Merger Agreement is terminated due to the Stockholder Approval not being obtained at a meeting of the Company's stockholders at which a vote is taken, the Company would be required to reimburse Novartis' reasonable out-of-pocket fees and expenses, up to $5.0 million, and any amounts reimbursed will be deducted from the amount of the termination fee payable by the Company, if any.

The Merger Agreement also provides that Novartis will be required to pay the Company a reverse termination fee of $150.0 million under certain specified circumstances, including, among others, the termination of the Merger Agreement if certain required regulatory approvals have not been obtained by the Outside Date or the termination of the Merger Agreement due to certain types of legal restraints on the Merger being imposed.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains certain statements that are forward-looking statements within the meaning of federal securities laws. When used in this report, the words "may," "will," "should," "could," "would," "anticipate," "estimate," "expect," "plan," "believe," "predict," "potential," "project," "target," "forecast," "intend," "working to" and simila are intended to identify forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include the important risks and uncertainties that may affect our future operations as discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, in our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2018, in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, in this Quarterly Report on Form 10-Q and in any other filings made with the Securities and Exchange Commission. Readers of this report are cautioned not to place undue reliance on these forward-looking statements. While we believe the assumptions on which the forward-looking statements are based are reasonable, there can be no assurance that these forward-looking statements will prove to be accurate. We undertake no obligation to revise or update any forward-looking statements for any reason to conform these statements to actual results or to changes in our expectations, except as otherwise required by law. This cautionary statement is applicable to all forward-looking statements contained in this report.

Factors that could cause actual results to differ materially from those in the forward-looking statements include:

- we or independent investigators may experience delays in the initiation, availability of data from, or completion of clinical trials and development programs (whether caused by competition, adverse events, patient enrollment rates, shortage of clinical trial materials, regulatory issues or other factors);
- suppliers or other third-party contractors may not fulfill their contractual obligations on a timely basis or at all;
- data from prior clinical trials may not be indicative of subsequent clinical trial results;
- lack of safety and/or efficacy of our product candidates;
- early stage pre-clinical data may not be indicative of subsequent data when expanded to additional pre-clinical models or to subsequent clinical data;
- evolving competitive activity and intellectual property landscape may impair our ability to capture value for the technology;
- our inability to maintain, protect and enhance our intellectual property;

· costs associated with defending intellectual property infringement and other claims;

· risks that expectations and estimates turn out to be incorrect, including estimates of the potential markets for our product candidates, estimates of the capacity of manufacturing and other facilities required to support our product candidates, supply chain issues of any type, including timing of supply, projected cash needs, projected timing of the use of cash, and expected future revenues, operations, expenditures and cash position; and

· risks and uncertainties related to the proposed acquisition, or the Merger, of us by Novartis AG, or Novartis, pursuant to the Agreement and Plan of Merger, or the Merger Agreement, among us, Novartis and Edinburgh Merger Corporation, a wholly owned subsidiary of Novartis:

o the risk that we are unable to consummate the Merger within the anticipated time period, or at all, due to the failure to obtain stockholder approval of the adoption of the Merger Agreement or failure to obtain the required regulatory approvals or satisfy the other conditions to the completion of the Merger;

- the risk that the Merger Agreement may be terminated in circumstances requiring us to pay Novartis a termination fee of $73.5 million;

- the risk of any event, change or other circumstances occurring that could give rise to the termination of the Merger Agreement;

- the risks that the proposed Merger disrupts our current plans and operations or affects our ability to retain or recruit key employees;

- the effect of the announcement or pendency of the Merger on our business relationships, operating results and business generally;

- the amount of the costs, fees, expenses and charges related to the Merger Agreement or the Merger;

- the risks related to diverting management's or employees' attention from ongoing business operations;

- the risks associated with limitations placed on our ability to operate our business under the Merger Agreement;

- the risk that our stock price may decline significantly if the Merger is not completed or may suffer as a result of uncertainty surrounding the Merger;

- the nature, cost and outcome of pending and future litigation and other legal proceedings, including any such proceedings related to the Merger and instituted against us and others; and

- the possibility that the companies may be adversely affected by other economic, business and/or competitive factors.

Overview

Certain amounts presented in this discussion and analysis are presented in thousands and may be rounded for purposes of calculating to the summed rounded amount.

Pending Merger

On October 17, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with Novartis AG, or Novartis, and Edinburgh Merger Corporation, a wholly owned subsidiary of Novartis, or Merger Sub, subject to the terms and conditions of which we will be acquired by Novartis for $24.00 per share in cash through the merger of Merger Sub with and into us, with us continuing as the surviving corporation and a wholly-owned subsidiary of Novartis, or the Merger. The consummation of the Merger is subject to certain closing conditions, including the requisite approval of our stockholders and the receipt of certain antitrust and regulatory approvals. See Note 13 –Subsequent Event of the Notes to Condensed Financial Statements contained herein for additional information regarding the Merger, and see “Risk Factors” in Part II, Item 1A herein for important information regarding certain risks associated with the Merger Agreement and the Merger.

We did not record significant expenses related to the Merger in the three or nine months ended September 30, 2018. However, we expect general and administrative expenses will increase for the three months ending December 31, 2018 and thereafter compared to the same prior year periods due to significant professional and legal costs that we have incurred, and expect to incur, related to the Merger.

Business Overview

We are a biopharmaceutical company and leader in developing targeted therapies for the treatment of cancer. We use drug conjugation technology to create novel therapeutics and companion imaging agents for personalized targeted therapies. Our agents actively target receptors that are over-expressed on diseased cells relative to healthy cells, such as prostate specific membrane antigen, or PSMA, in prostate cancer. This targeted approach is designed to safely enable the delivery of highly potent drug payloads. The companion imaging agents are designed to identify patients whose disease over-expresses the target of the therapy and who are therefore more likely to benefit from treatment.

In September 2017, we entered into a Development and License Agreement, or the License Agreement, with ABX advanced biochemical compounds — Biomedizinische Forschungsreagenzien GmbH, or ABX, pursuant to which we acquired exclusive worldwide rights to develop and commercialize PSMA-617 agents, including the product candidate known as 177Lu-PSMA-617, a radioligand therapeutic, or RLT. Under the terms of the License Agreement, we will be responsible for, and bear the future costs of, worldwide development and commercialization of PSMA-617. As consideration for the exclusive license, we made an upfront cash payment on September 29, 2017 of approximately $11.9 million to ABX, consisting of $12.0 million less an immaterial expense reimbursement amount, and issued to ABX 2,000,000 shares of our common stock and warrants to purchase, in the aggregate, 4,000,000 shares of our common stock. The License Agreement also obligates us to pay ABX regulatory milestone payments of up to $25.0 million, sales milestone payments of up to $135.0 million, and tiered royalties, beginning in the mid-teens and not to exceed the mid-twenties, based on percentages of net sales. We recorded $16.5 million of acquired in-process research and development, or IPR&D, expenses related to the License Agreement in 2017 consisting of the following:

- $12.0 million related to the upfront payment to ABX;
- $3.8 million related to the fair value of common stock and warrant shares issued; and
- $0.7 million of acquisition costs consisting primarily of legal and professional fees.

In October 2017, we announced our plan to focus our resources on the development of 177Lu-PSMA-617 and on a targeted effort to generate proof-of-concept data for our EC17 adaptor-controlled chimeric antigen receptor T-cell, or EC17/CAR T-cell, therapy program, and to explore out-licensing opportunities for all other development programs.

In the three months ended June 30, 2018, we initiated enrollment of the VISION trial, an international, prospective, open-label, multicenter, randomized phase 3 study of 177Lu-PSMA-617 enrolling up to 750 patients with progressive PSMA-positive metastatic castration-resistant prostate cancer, or mCRPC. 177Lu-PSMA-617 utilizes a high affinity targeting ligand to direct potent radiotherapy to prostate cancer cells. The specific targeting of this therapy comes from the "ligand" portion of the RLT, which is a small molecule designed to bind to PSMA, a protein highly expressed on the cell surface of most prostate cancer cells but absent on most normal cells. The PSMA targeting

ligand in 177Lu-PSMA-617 is chemically attached to a therapeutic radioactive atom called Lutetium-177 (177Lu), which releases an energetic beta particle designed to precisely deliver cell-killing radiation to the site of disease. Unlike traditional external beam radiotherapy, 177Lu-PSMA-617, which is administered as a systemic injection, has been designed to directly target multiple sites of PSMA-positive prostate cancer throughout the body, including the bone and soft tissue, while bypassing the PSMA-negative cells. Prior to treatment with 177Lu-PSMA-617, the patient's expression of PSMA can be determined using imaging technology, allowing for personalization of treatment so that the optimum course of therapy might be selected. As highlighted in roughly 20 peer reviewed publications of trials in the post-chemotherapy compassionate use setting, 177Lu-PSMA-617 demonstrated a prostate-specific antigen, or PSA, response (defined as greater than 50% decline from baseline) in 40% to 60% of patients, and a Response Evaluation Criteria in Solid Tumors, or RECIST, response rate in soft tissue disease of between 40% and 50%.

In October 2017, we entered into an agreement with RadioMedix, Inc., a biotechnology company focused on innovative targeted radiopharmaceuticals for diagnosis, monitoring and therapy of cancer, which enabled the transfer of a U.S. Investigational New Drug, or IND, application of 177Lu-PSMA-617 from the prior sponsor, RadioMedix, to us. This transfer helped accelerate our successful End of Phase 2 trial meeting with the FDA in early 2018 to confirm our phase 3 trial design and registration plan for 177Lu-PSMA-617.

In September 2018, we announced that, following a meeting with the U.S. Food and Drug Administration, or the FDA, it was determined that radiographic progression free survival, or rPFS, is an appropriate efficacy endpoint in our

ongoing phase 3 VISION trial to support the submission of a New Drug Application, or NDA, for full FDA approval of 177Lu-PSMA-617 for the treatment of mCRPC. The updated trial protocol will reflect this determination on rPFS while retaining the final, fully powered overall survival, or OS, analysis. We expect to complete the analysis of rPFS before the end of 2019 and to complete the analysis of OS near the end of 2020.

Under the updated VISION trial design, the two interim assessments previously planned at 50% and 70% of OS events will be replaced with a single assessment of rPFS. This assessment is expected to occur at approximately the same time that the first interim OS assessment would have occurred under the prior trial design and shortly after the time the trial is fully enrolled. If 177Lu-PSMA-617 meets the primary endpoint in the rPFS assessment, no unexpected safety issues arise, and it demonstrates no detriment in OS relative to the control arm, we intend to submit an NDA to seek full approval in the United States. The rPFS analysis will include approximately 450 rPFS events. Regardless of the outcome of the rPFS assessment, we intend to continue to follow patients in the VISION trial in order to assess the final OS alternative primary endpoint. An efficacy analysis of OS will be conducted at approximately 490 events. Other aspects of the VISION trial design, including patient treatment and assessments, study size, overall duration, and follow up remain unchanged. Secondary endpoints include RECIST response and time to first symptomatic skeletal event.

In July 2018, we entered into a Global Supply Agreement, or the Supply Agreement, with ITG Isotope Technologies Garching GmbH, or ITG. The Supply Agreement supersedes the clinical supply agreement for the same product that we announced on February 26, 2018. Under the Supply Agreement, ITG agrees to supply us with, and we agree to purchase, 100% of the no-carrier-added lutetium-177, or the Product, required for our phase 3 VISION trial. We also agree to purchase, and ITG agrees to supply, at least 50%, and up to 100% at our request, of our Product needs for 177Lu-PSMA-617 during the commercial phase, which begins upon the first commercial country launch of 177Lu-PSMA-617 following receipt of a full marketing authorization allowing sale of such product in that first country. Pursuant to the Supply Agreement we made a one-time, upfront payment of 5 million Euros, or $5.8 million, to ITG on August 2, 2018. The Supply Agreement also sets forth various terms relating to the manufacture, ordering, supply and payment regarding the Product.

In October 2017, we entered into a three-party agreement with the University of Sydney, or the University, and ANZUP, a cooperative cancer trials group operating in Australia and New Zealand pursuing research in genito-urinary malignancies, in which ANZUP sponsors jointly with the University a randomized phase 2 multi-center TheraP trial of 177Lu-PSMA-617 versus cabazitaxel in 200 mCRPC patients. The TheraP trial commenced enrollment in the first quarter of 2018. Under the three-party agreement, we provide product and financial support for the trial. We will have access to data generated from the trial, which is a potentially important supportive trial for future regulatory submissions. The primary financial obligations of the trial, along with labeling PSMA-617 with Lutetium-177, will be the responsibility of the University and ANZUP.

In May 2018, The Lancet Oncology published updated data from a phase 2 investigator-initiated trial of 30 patients with PSMA-positive mCRPC treated with 177Lu-PSMA-617. Preliminary results of this trial were previously announced at the 2017 European Society for Medical Oncology, or ESMO, Congress and presented by Professor Michael Hofman of the Peter MacCallum Cancer Centre in Melbourne, Australia. This publication provided a more

comprehensive summary than previously disclosed of patient characteristics, treatment regimen and more mature outcome data, including updated Kaplan-Meier curves estimating OS and PSA progression-free survival, or PFS, as well as a swimmer's plot of the 30 patients. This study evaluated a heavily pre-treated patient population, 87% of which had received ≥ 1 line of prior chemotherapy (80% docetaxel and 47% cabazitaxel) and 83% of which had received prior treatment with abiraterone acetate and/or enzalutamide. Observations in this study included a PSA reduction of at least 50% from baseline, or PSA50, in 57% of patients, a PSA reduction of at least 80% from baseline, or PSA80, in 43% of patients and a PSA reduction of ≥ 96% in 20% of patients which were identified as "exceptional responders". Regarding disease progression and survival, a median PSA PFS of 7.6 months and a median OS of 13.5 months were observed. Both the median PSA PFS and the median OS reflect improved outcomes versus the 6.3 months and 12.7 months for each endpoint, respectively, previously presented at the 2017 ESMO Congress. Notably, patients with a PSA50 response had improved median PSA PFS of 9.9 months and median OS of 17.0 months compared to PSA PFS of 4.1 months and median OS of 9.9 months for those patients who did not achieve a PSA50 response. Additionally, clinically meaningful improvements in quality of life measures were observed. Seventeen patients (57%) had prostate cancer working group 2, or PCWG2, RECIST 1.1 evaluable nodal or visceral target lesions following CT scan at baseline. Confirmed objective responses were seen in 14 (82%) of these 17 patients, including complete and partial response rates of 29% and 53%, respectively. The journal noted that 177Lu-PSMA-617 was well tolerated, with no significant dose-limiting toxicities observed. The most common treatment-related toxicity was Grade 1 xerostomia, commonly referred to as dry mouth, seen in 87% of patients, which is higher than previously reported (63%), but generally did not require any intervention.

The occurrence of treatment-related Grade 3-4 hematologic toxicity was low and comparable to the largest retrospective published cohort. On May 16, 2018, we announced updated data on the additional 20 patient expansion cohort in the phase 2 trial of 177Lu-PSMA-617. In the 50 patients receiving 177Lu-PSMA-617, 62% had a greater than 50% reduction in their PSA levels and 44% had a PSA reduction of 80% or greater.

We are also developing a unique therapeutic approach that involves the re-targeting of potent immune cells, called CAR T-cells, to fight cancer. CAR T-cell therapies may be characterized as either allogeneic CAR T-cells, which are those that are engineered using T-cells from a single donor that are utilized in multiple patients, or autologous CAR T-cells, which are those that are engineered using a patient's own T-cells. Our program utilizes an autologous approach. Traditional CAR T-cell therapies rely on the activity and specificity of T-cells that have been engineered to recognize a single naturally expressed target that, ideally, is only present on cancer cells, with no cross-reactivity to or targeting of healthy tissues. Our alternative strategy relies on a single universal CAR T-cell that expresses a high affinity for a molecule called fluorescein isothiocyanate, or FITC, which is not naturally present in the human body. The activity and specificity of these universal CAR T-cells is dependent upon the administration of our proprietary CAR T adaptor molecules, or CAMs, that "paint" a patient's cancer cells with FITC by conjugating it to a tumor-targeting ligand. The FITC molecule then attracts the universal CAR T-cell to the site of disease, causing the anti-cancer immune response of a traditional CAR T-cell therapy. However, unlike existing CAR T-cell technologies, our unique CAM-dependent technology makes possible the engineering of a single universal CAR T-cell that can be used to treat a wide range of cancer types. This is accomplished through the use of multiple CAMs, each of which is designed to bind the FITC molecule to a specific cancer type. In addition to enabling the treatment of multiple cancer types with a single universal CAR T-cell, this adaptor technology is also designed to facilitate novel control strategies intended to increase the safety of CAR T-cell therapy. In March 2017, we announced our collaboration with Seattle Children's Research Institute, or SCRI, and Dr. Michael Jensen for the development of our technology in the CAR T-cell immunotherapy setting, in which we use EC17 as the CAM. The aim of the research collaboration is to join our adapter technology with the CAR T-cell immunotherapy research efforts at the Ben Towne Center for Childhood Cancer Research at SCRI, to move these potentially enabling technologies more quickly to patients in the clinic. In October 2017, we announced that we are limiting the scope of our EC17/CAR T-cell therapy program to a targeted effort to generate proof-of-concept data. Pre-clinical evaluations have been completed, and the IND application is expected to be filed in the fourth quarter of 2018.

In June 2017, we ended clinical development of EC1456, our second-generation folate-targeted product candidate, and stopped enrollment in our EC1456 phase 1b trial as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. In December 2017, we stopped enrollment in our EC1456 ovarian cancer surgical trial. In addition, in June 2017, we narrowed the focus of our phase 1 EC1169 (a PSMA-targeted product candidate) development program (for which enrollment was completed in October 2017, but for which we currently do not intend to invest further resources beyond the completion of the phase 1 taxane-exposed cohort), refocused our efforts on pre-clinical programs, and reduced our workforce by approximately 40% to align resources to focus on our highest value opportunities while maintaining key capabilities. We recorded $2.3 million of restructuring expenses in the nine months ended September 30, 2017, as follows:

- included in research and development expenses were expenses for employee termination benefits of $0.9 million, $0.9 million for the remaining EC1456 phase 1b trial expenses, including site close-out expenses, $0.3 million related to other restructuring expenses, and $0.1 million related to fixed asset impairment charges; and

· included in general and administrative expenses were expenses for employee termination benefits of $0.1 million.

As of June 30, 2018, we had paid all severance and other costs related to the restructuring activities.

At December 31, 2017, we had a clinical trial accrual balance related to the EC1456 phase 1b trial termination of $106,900. There were no material adjustments to the EC1456 phase 1b trial termination accrual balance during the three and nine months ended September 30, 2018, and payments made against the accrual in those periods were $14,800 and $106,900, respectively. As of September 30, 2018, there was no remaining accrual balance related to the restructuring activities and all payments had been made.

Summary of Financial Results

For the nine months ended September 30, 2018, we had a net loss of $32.8 million compared to a net loss of $46.5 million for the nine months ended September 30, 2017. We had a retained deficit of $341.4 million at September 30, 2018. We expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and, potentially, the commercialization processes. Our operating costs were lower for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 primarily due to a decrease in acquired IPR&D expenses related to the License Agreement for PSMA-617 that we entered into in September 2017, decreases in trial related expenses for EC1169 and EC1456 and decreases in pre-clinical work and general research. These decreases were partially offset by increases in expenses related to PSMA-617 development, including expenses related to the phase 3 VISION trial, increases in stock-based compensation expense, increases in general and administrative fees, including legal and professional fees and increases in expenses related to the EC17/CAR T-cell therapy program.

As of September 30, 2018, our cash, cash equivalents and investments were $344.2 million, which included $269.8 million of net proceeds from our public offerings of 20,535,714 and 10,878,379 shares of our common stock that closed in March and September of 2018, respectively.

Critical Accounting Policies

Our significant accounting policies are described in more detail in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in Note 2 – Significant Accounting Policies of the Notes to Condensed Financial Statements contained in Part I, Item 1 herein. Other than the adoption of Accounting Standards Update 2014-09, Revenue from Contracts with Customers (Topic 606), or ASC 606, effective January 1, 2018 as discussed in Note 3 – New Accounting Pronouncements of the Notes to Condensed Financial Statements contained in Part I, Item 1 herein, there were no changes in the three and nine months ended September 30, 2018 to the application of the accounting policies that are critical to the judgments and estimates used in the preparation of our condensed financial statements.

Results of Operations

Comparison of Three Months Ended September 30, 2017 to Three Months Ended September 30, 2018

	Three Months Ended September 30,		$ Increase/ (Decrease)	% Increase/ (Decrease)	
	2017	2018			
	(In thousands)				
Statement of operations data:					
Collaboration revenue	$ 33	$ 86	$ 53	161	%
Operating expenses:					
Research and development	4,090	8,856	4,766	117	%
General and administrative	3,011	4,789	1,778	59	%
Acquired in-process research and development	16,493	—	(16,493)	(100)	%
Total operating expenses	23,594	13,645	(9,949)	(42)	%
Loss from operations	(23,561)	(13,559)	10,002	42	%
Interest income, net	265	959	694	262	%
Other income (expense), net	29	(8)	(37)	(128)	%
Net loss	$ (23,267)	$ (12,608)	$ 10,659	46	%

Revenue

Our revenue in the three months ended September 30, 2017 and the three months ended September 30, 2018 included the amortization of the $1.0 million non-refundable upfront payment from Nihon Medi-Physic Co., LTD, or NMP, as well as an annual minimum royalty payment of $20,000 received in each of the three months ended September 30, 2017 and 2018. In addition, revenue for the three months ended September 30, 2018 included a $50,000 annual fee that we received pursuant to the Clinical Supply and License Option Agreement that we entered into in August 2018 with BlinkBio.

Research and Development

The increase in research and development expenses for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 was primarily attributable to: an increase of $4.5 million in expenses related to the development of PSMA-617, including expenses related to the phase 3 VISION trial; an increase of $1.2 million in compensation expense, of which $0.4 million related to stock-based compensation charges; and an increase of $0.1 million related to our EC17/CAR T-cell therapy program. The increases were partially offset by a decrease of $0.8 million in EC1169 trial expenses; and a decrease of $0.2 million for general research.

Included in research and development expenses were stock-based compensation charges of $0.3 million and $0.7 million for the three months ended September 30, 2017 and 2018, respectively.

Research and development expenses included expenses of $0.2 million for each of the three months ended September 30, 2017 and 2018, for company-funded research at Purdue University, the primary employer of our Chief Science Officer.

General and Administrative

The increase in general and administrative expenses for the three months ended September 30, 2018 compared to the three months ended September 30, 2017 was primarily attributable to: an increase of $0.8 million in compensation expense, of which $0.5 million related to stock-based compensation charges; an increase of $0.6 million in legal and professional fees; and an increase of $0.4 million in other general and administrative fees.

Included in general and administrative expenses were stock-based compensation charges of $0.4 million and $0.9 million for the three months ended September 30, 2017 and 2018, respectively.

Acquired In-Process Research and Development

The acquired IPR&D expenses in the three months ended September 30, 2017 related to the expenses incurred as a result of the License Agreement. We recorded $16.5 million of acquired IPR&D expenses in the three months ended September 30, 2017, which included $12.0 million for an upfront payment to ABX, $3.8 million related to the fair value of common stock and warrant shares issued, and $0.7 million related to acquisition costs consisting primarily of legal and professional fees. We did not record any acquired IPR&D expenses in the three months ended September 30, 2018.

Interest Income, Net

The increase in interest income, net in the three months ended September 30, 2018 compared to the three months ended September 30, 2017 resulted from an increase of $0.6 million due to higher average short-term investment balances in the three months ended September 30, 2018 as compared to the same prior year period and an increase of $0.1 million in the interest rate yield during the three months ended September 30, 2018 as compared to the three months ended September 30, 2017. There were no long-term investment balances at September 30, 2017 or 2018.

Other Income (Expense), Net

The change in other expense, net in the three months ended September 30, 2018, compared to other income, net in the three months ended September 30, 2017 was primarily due to a loss on the disposal of property and equipment in the three months ended September 30, 2018 compared to a gain on the disposal of property and equipment in the three months ended September 30, 2017.

Comparison of Nine Months Ended September 30, 2017 to Nine Months Ended September 30, 2018

	Nine Months Ended September 30,		$ Increase/ (Decrease)	% Increase/ (Decrease)	
	2017	2018			
	(In thousands)				
Statement of operations data:					
Collaboration revenue	$ 58	$ 116	$ 58	100	%
Operating expenses:					
Research and development	20,739	21,736	997	5	%
General and administrative	10,062	13,198	3,136	31	%
Acquired in-process research and development	16,493	—	(16,493)	(100)	%
Total operating expenses	47,294	34,934	(12,360)	(26)	%
Loss from operations	(47,236)	(34,818)	12,418	26	%
Interest income, net	734	2,092	1,358	185	%
Other income (expense), net	2	(49)	(51)	(2,550)	%
Net loss	$ (46,500)	$ (32,775)	$ 13,725	30	%

Revenue

Our revenue in the nine months ended September 30, 2017 and the nine months ended September 30, 2018 included the amortization of the $1.0 million non-refundable upfront payment from NMP, as well as an annual minimum royalty payment of $20,000 received in each of the nine months ended September 30, 2017 and 2018. In addition, revenue for the nine months ended September 30, 2018, included a $50,000 annual fee that we received pursuant to the Clinical Supply and License Option Agreement that we entered into in August 2018 with BlinkBio.

Research and Development

The increase in research and development expenses for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was primarily attributable to: an increase of $8.6 million in expenses related to the development of PSMA-617, including expenses related to the phase 3 VISION trial; an increase of $0.5 million in expenses related to the EC17/CAR T-cell therapy program; and an increase of $0.2 million in compensation expense. These expenses were in large part offset by: a decrease of $3.1 million in EC1169 trial expenses; a decrease of $2.8 million in expenses related to pre-clinical work and general research; and a decrease of $2.4 million in expenses related to the EC1456 trial.

Included in research and development expenses were stock-based compensation charges of $1.4 million and $2.0 million for the nine months ended September 30, 2017 and 2018, respectively.

Research and development expenses included expenses of $0.6 million and $0.5 million for the nine months ended September 30, 2017 and 2018, respectively, for company-funded research at Purdue University, the primary employer of our Chief Science Officer.

General and Administrative

The increase in general and administrative expenses for the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 was primarily due to: an increase of $1.6 million in compensation expense, of

which $1.1 million related to stock-based compensation; an increase of $1.2 million related to legal and professional fees; and an increase of $0.3 million in other general and administrative fees.

Included in general and administrative expenses were stock-based compensation charges of $1.2 million and $2.3 million for the nine months ended September 30, 2017 and 2018, respectively.

Acquired In-Process Research and Development

The acquired IPR&D expenses in the nine months ended September 30, 2017 related to the expenses incurred as a result of the License Agreement. We recorded $16.5 million of acquired IPR&D expenses in the nine months ended September 30, 2017, which included $12.0 million for an upfront payment to ABX, $3.8 million related to the fair value of common stock and warrant shares issued, and $0.7 million related to acquisition costs consisting primarily of legal and professional fees. We did not record any acquired IPR&D expenses in the nine months ended September 30, 2018.

Interest Income, Net

The increase in interest income, net in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017 resulted from an increase of $0.9 million in the interest rate yield during the nine months ended September 30, 2018 as compared to the nine months ended September 30, 2017 and an increase of $0.5 million due to higher average short-term investment balances. There were no long-term investment balances at September 30, 2017 or 2018.

Other Income (Expense), Net

The change in other expense, net in the nine months ended September 30, 2018, compared to other income, net in the nine months ended September 30, 2017 was primarily due to an increase in charitable contributions in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017.

Liquidity and Capital Resources

We have funded our operations principally through sales of equity and debt securities, revenue from strategic collaborations, grants, and loans. As of September 30, 2018, we had cash, cash equivalents and investments of $344.2 million, which included $269.8 million of net proceeds from our public offerings of 20,535,714 and 10,878,379 shares of our common stock that closed in March and September of 2018, respectively. The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Nine Months Ended September 30,	
	2017	2018
	(in thousands)	
Net cash used in operating activities	$ (27,413)	$ (34,287)
Net cash provided by (used in) investing activities	38,743	(196,659)
Net cash provided by financing activities	4,620	279,655
Net increase in cash and cash equivalents	$ 15,950	$ 48,709

Operating Activities

The cash used in operating activities for the nine months ended September 30, 2017 and 2018 primarily resulted from our net loss adjusted for non-cash items and changes in operating assets and liabilities, which included the $5.8 million upfront payment to ITG.

Investing Activities

The cash provided by investing activities during the nine months ended September 30, 2017 was due to the net result of maturities and purchases of investments of approximately $51.1 million, which was partially offset by the purchase of acquired IPR&D of approximately $12.3 million and capital expenditures for equipment of approximately $47,000. The cash used in investing activities during the nine months ended September 30, 2018 was due to the net

result of purchases and maturities of investments of approximately $196.7 million, resulting primarily from the use of funds from our equity offerings, capital expenditures for equipment of approximately $43,000, and proceeds of approximately $90,000 from the disposal of property and equipment.

Financing Activities

The cash provided by financing activities during the nine months ended September 30, 2017 consisted of approximately $4.6 million of net proceeds from the exercise of a warrant, approximately $0.1 million of net proceeds from the exercise of stock options and approximately $48,000 of net proceeds from stock purchases under our employee stock purchase plan, which were partially offset by approximately $0.1 million of stock repurchases for restricted stock units, or RSUs, that vested during the period. The cash provided by financing activities during the nine months ended September 30, 2018 consisted of approximately $269.8 million of net proceeds from our public offerings of common stock that closed in March and September of 2018, approximately $9.8 million of net proceeds from the exercise of stock options, and approximately $0.1 million of net proceeds from stock purchases under our employee stock purchase plan, which were partially offset by approximately $0.1 million of stock repurchases for RSUs that vested during the period.

Operating Capital Requirements

We expect to continue to incur significant operating losses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and, potentially, the commercialization processes.

As of September 30, 2018, our cash, cash equivalents and investments were $344.2 million, which included $269.8 million of net proceeds from our public offerings of 20,535,714 and 10,878,379 shares of our common stock that closed in March and September of 2018, respectively. We believe that our current cash balance will be sufficient to fund our activities for at least the next 12 months, which include our focus on clinical development of 177Lu-PSMA-617 and our effort to generate proof-of-concept data for our EC17/CAR T-cell therapy program, but because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
-

the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;

- the cost of manufacturing any product candidates we successfully commercialize;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, payments, receipts and amount of sales of, or royalties on, our product candidates, if any; and
- the costs we may incur and revenues we may generate in connection with in-licensing and out-licensing activities.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt financings or other sources, such as strategic partnerships or licensing arrangements. The sale of additional equity securities by us would result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or convertible preferred stock, these securities may have rights senior to those of our common stock and could contain covenants that would restrict our operations. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs, or enter into collaboration or other arrangements with other companies to provide such funding for one or more of such clinical trials or programs in exchange for our affording such partner commercialization or other rights to the product candidates that are the subject of such clinical trials or programs. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us.

Contractual Obligations and Commitments

There have been no significant changes during the nine months ended September 30, 2018 to the items that we disclosed as our contractual obligations and commitments in our Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

None.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2018, we had cash, cash equivalents and investments of $344.2 million. The investments consisted primarily of U.S. Treasuries, corporate debt securities and cash equivalents. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our short-term investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, we believe that an immediate 10 percent change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our short-term investments until maturity, and therefore we do not expect that our results of operations or cash flows would be adversely affected by any change in market interest rates on our investments. We carry our investments based on publicly available information. We do not currently have any investment securities for which a market is not readily available or active.

We do not believe that any credit risk is likely to have a material impact on the value of our assets and liabilities.

We contract with contract research organizations, contract manufacturing organizations and investigational sites globally. We may be subject to fluctuations in foreign currency rates in connection with these agreements. We believe that a 10 percent fluctuation in foreign currency rates would not have a material impact on our financial statements. We currently do not hedge our foreign currency exchange risk, but as our operations in foreign countries expand we may consider the use of hedges.

Item 4. Controls and Procedures

Conclusion Regarding Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date are effective at the reasonable assurance level in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the three months ended September 30, 2018, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

See Note 10 – Commitments and Contingencies of the Notes to Condensed Financial Statements contained herein for information regarding certain legal proceedings affecting us, which information is incorporated herein by reference.

Item 1A. Risk Factors

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition, results of operations, cash flows or stock price. If any of these risks or uncertainties actually occurs, our business, financial condition, results of operations, cash flows or stock price could be materially and adversely affected.

Risk factors below that did not appear, or have been modified from the version of that risk factor as it appeared, in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2018, are noted with an "*" preceding such risk factor.

Risks Related to the Merger

*Uncertainties associated with the Merger may cause a loss of management and other key employees and disrupt our business relationships, which could adversely affect our business.

Uncertainty about the effects of the Merger on our employees, partners and suppliers may have an adverse effect on our business. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Merger is completed and for a period of time thereafter. Employee retention may be particularly challenging during the pendency of the Merger. In addition, we have diverted, and will continue to divert, significant management resources towards the completion of the Merger, which could materially adversely affect our business and operations.

If key employees depart, our business relationships may be subject to disruption as third parties attempt to negotiate changes in existing business relationships or consider entering into business relationships with parties other than us. If key employees depart or if our existing business relationships suffer, our results of operations may be adversely affected. The adverse effects of such disruptions could be further exacerbated by any delay in completing the Merger.

*We are subject to contractual restrictions while the Merger is pending, which could adversely affect our business.

The Merger Agreement requires us to act in the ordinary course of business and restricts us, without the consent of Novartis, from taking certain specified actions until the proposed Merger occurs or the Merger Agreement is terminated. These restrictions may prevent us from pursuing otherwise attractive business opportunities and making other changes to our business before completion of the Merger or, if the Merger is not completed, termination of the Merger Agreement.

*We have incurred, and will continue to incur, significant transaction and related costs in connection with the Merger.

We have incurred and expect to continue to incur significant costs, fees and expenses in connection with the proposed Merger, most of which are payable by us regardless of whether or not the Merger is consummated. If the Merger is not consummated, we may under certain circumstances be required to pay to Novartis a termination fee of $73.5 million. If the Merger is not consummated as a result of the failure to obtain the requisite vote of our stockholders adopting the Merger Agreement, we will be required to pay to Novartis an amount equal to Novartis' reasonable out-of-pocket fees and expenses incurred in connection with the Merger, up to a maximum amount of $5.0 million. Our financial position and results of operations would be adversely affected if we were required to pay the termination fee to Novartis.

*A failure to complete the Merger or a significant delay in completing the Merger could negatively impact the price of our common stock, as well as our future business and financial results.

The Merger Agreement contains a number of conditions that must be satisfied or waived prior to the completion of the Merger. We cannot assure you that all of the conditions to the Merger will be so satisfied or waived. If the conditions to the Merger are not satisfied or waived, or if other events intervene that delay or result in the termination of the Merger Agreement, we may be unable to complete the Merger or to complete the Merger in a timely manner. We cannot guarantee that the Merger will be completed, or that it will be completed as currently proposed, or at any particular time.

Legal proceedings instituted against us and others relating to the Merger also could delay or prevent the Merger from being completed. To date, one complaint relating to the Merger has been filed by a purported stockholder of the Company seeking, among other things, injunctive relief enjoining the consummation of the Merger unless and until material information that was allegedly omitted from the Company's preliminary proxy statement related to the Merger is disclosed. If the lawsuit is not resolved on a timely basis, it could delay consummation of the Merger and result in additional costs to the Company. There can be no assurance that there will not be any additional lawsuits filed against the Company and/or its directors and officers in connection with the Merger.

If the Merger is not completed, our ongoing business may be adversely affected by negative reactions from the financial markets (including negative impacts on the market price of our common stock) and from our employees, business partners and other third parties.

Additionally, in approving the Merger Agreement, our Board of Directors and the Special Committee of our Board of Directors considered a number of factors and potential benefits, including the fact that the consideration to be received by holders of our common stock in the Merger represented a 54% premium to the closing price of our common stock of $15.56 on October 17, 2018. If the Merger is not completed, the holders of our common stock will not realize this potential benefit of the Merger.

*The Merger Agreement limits our ability to pursue alternatives to the Merger and may discourage other companies from trying to acquire us for greater consideration than what Novartis has agreed to pay.

The Merger Agreement contains provisions that make it more difficult for us to sell our business to a company other than Novartis. These provisions include a general prohibition on us soliciting any acquisition proposal or offer for a competing transaction. If we or Novartis terminate the Merger Agreement and we agree to be or are subsequently acquired by another company, we may in some circumstances be required to pay to Novartis a termination fee of $73.5 million. Further, our Board of Directors has agreed in the Merger Agreement, subject to limited exceptions, that it will not withdraw or modify in a manner adverse to Novartis its recommendation that our stockholders adopt the

Merger Agreement.

These provisions might discourage a third party that has an interest in acquiring all or a significant part of our company from considering or proposing an acquisition, even if the party were prepared to pay consideration with a higher per share cash or market value than the cash value of the Merger consideration, or might result in a potential competing acquirer proposing to pay a lower price than it might otherwise have proposed to pay because of the added expense of the termination fee that may become payable in certain circumstances.

Risks Related to Our Business and Industry

*We have incurred significant losses in each year since our inception, other than in 2014, and we anticipate that we will continue to incur significant losses for the foreseeable future. We may never again achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have not generated any revenue from product sales to date. For the nine months ended September 30, 2018, we had a net loss of $32.8 million and a retained deficit of $341.4 million. We expect to continue to incur significant operating expenses for the next several years as we pursue the advancement of our product candidates through the research, development, regulatory and commercialization processes. As such, we are subject to all of the risks incident to the creation of new biopharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. If our product candidates fail in clinical trials, or do not gain regulatory approval, or fail to achieve market acceptance, we may never again be profitable. Even if we achieve profitability again in the future, we may not be able to sustain profitability in subsequent periods.

*We currently have no approved products, which makes it difficult to assess our future viability.

To date, we have not derived any revenue from the sales of our products. Our operations to date have been limited to acquiring, developing and securing our technology, undertaking pre-clinical studies and clinical trials of our product candidates and engaging in research and development under collaboration agreements. We have not yet demonstrated an ability to obtain regulatory approval, formulate and manufacture commercial-scale products, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, it is difficult to predict our future success and the viability of any commercial programs that we may choose to take forward. We have no current sources of revenue except for the recognition of remaining deferred revenue related to the upfront payment under the agreement with Nihon Medi-Physic Co., LTD and annual payments under agreements with On Target Laboratories, L.L.C. and BlinkBio.

We are highly dependent on the success of PSMA-617 product candidates, and we cannot give any assurance that we will successfully complete its clinical development, or that it will receive regulatory approval or be successfully commercialized.

In September 2017, we entered into a License Agreement with ABX, pursuant to which we acquired exclusive worldwide rights to develop and commercialize PSMA-617, including the drug candidate known as 177Lu-PSMA-617, an RLT. In the three months ended June 30, 2018, we initiated enrollment of the VISION trial, an international, prospective, open-label, multicenter, randomized phase 3 study of 177Lu-PSMA-617 enrolling up to 750 patients with progressive PSMA-positive mCRPC. The VISION trial may not be successful, and

177Lu-PSMA-617 may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals for 177Lu-PSMA-617 from the FDA or other regulatory authorities if our clinical development programs for 177Lu-PSMA-617 fail to demonstrate that it is safe and effective to the satisfaction of such authorities, or if we have inadequate financial or other resources to advance 177Lu-PSMA-617 through the necessary development activities. Even if 177Lu-PSMA-617 receives regulatory approval, we may not be successful in marketing it for a number of reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts. Any failure to obtain approval of 177Lu-PSMA-617 and successfully commercialize it would have a material and adverse impact on our business.

We cannot give any assurance that we will successfully complete the clinical development of any of our other product candidates, or that they will receive regulatory approval or be successfully commercialized.

We have terminated or significantly limited the development programs for product candidates other than PSMA-617 and EC17/CAR T-cell therapy product candidates. With respect to any other product candidates that we may pursue, they may never receive regulatory approval or be successfully commercialized. We may fail to obtain necessary marketing approvals from the FDA or other regulatory authorities if our clinical development programs fail to demonstrate that they are safe and effective to the satisfaction of such authorities, or if we have inadequate financial or other resources to advance our product candidates through the necessary development activities. Even if any of our product candidates receive regulatory approval, we may not be successful in marketing them for a number of reasons, including the introduction by our competitors of more clinically-effective or cost-effective alternatives or failure in our sales and marketing efforts.

The results of clinical trials may not be predictive of future results, and those trials may not satisfy the requirements of the FDA or other regulatory authorities.

The clinical trials of our product candidates are, and the manufacturing and marketing of any approved products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States, Europe and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each indication for which we intend to market such product candidate. This process takes many years and requires the expenditure of substantial financial and human resources and may include post-marketing trials and surveillance. To date, we have not completed any randomized phase 3 clinical trials.

Positive results from pre-clinical studies and early clinical trials, such as those of 177Lu-PSMA-617, should not be relied upon as evidence that later-stage or large-scale clinical trials will succeed. Like our past history with respect to certain product candidates, a number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, even after promising results in earlier trials. We will be required to demonstrate with substantial evidence through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in the target population before the regulatory authorities will approve our product candidates for commercial sale, and we cannot assure you that we will be able to do so.

In addition to the phase 3 clinical trial of 177Lu-PSMA-617 that we initiated in the three months ended June 30, 2018, certain third party investigators, including Dr. Michael Hofman of the Peter MacCallum Cancer Center in Melbourne, Australia, are conducting clinical trials of 177Lu-PSMA-617 and other product candidates containing PSMA-617. In addition, the German institutions that own the patent rights to PSMA-617 have retained the right, under their license to ABX (under which we are the exclusive sublicensee), to conduct clinical trials of compounds containing

PSMA-617 at their premises in Heidelberg, Germany, subject to our approval of the trial protocol. Current or possible future clinical trials of compounds containing PSMA-617 that are conducted by third party investigators outside of our control (in whole or in part) may generate clinical data that hinders our ability to obtain regulatory approvals for the development and/or commercialization of 177Lu-PSMA-617.

Further, our product candidates may not be approved even if they achieve the primary endpoints in phase 3 clinical trials or registration trials. The FDA or other regulatory authorities may disagree with our trial design or the interpretation of data from pre-clinical studies and clinical trials. In addition, the FDA and other regulatory authorities may change requirements for the approval of our product candidates even after reviewing and providing non-binding comments on a protocol for a pivotal phase 3 clinical trial that has the potential to result in approval. Regulatory authorities may also approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

There is a high risk that our development and clinical activities will not result in commercial products, and we may be required to invest significant additional resources in our current development and clinical programs, to the exclusion of others, before it is known whether one or more of our product candidates will receive regulatory approval or be commercially introduced.

Our product candidates are in various stages of development and are prone to the risks of failure inherent in biopharmaceutical development. Development of our product candidates could be discontinued due to insufficient efficacy or unacceptable toxicity. In many cases, even if we ultimately obtain regulatory approval to market a product candidate, we will need to complete significant additional clinical trials before we can demonstrate that the product candidate is safe and effective to the satisfaction of the regulatory authorities involved. Clinical trials are expensive and uncertain processes that take years to complete. Failure can occur at any stage of the process. Further, even if a product candidate receives the required regulatory approvals, we cannot assure you that it will be successful commercially. In addition, while we invest in the technology and indications that we believe are most promising, financial and resource constraints may require us to forego or delay opportunities that may ultimately have greater commercial potential than those programs we are currently actively developing.

We may not achieve research, development and commercialization goals in the time frames that we publicly estimate, which could have an adverse impact on our business and could cause our stock price to decline.

We set goals, and make public statements regarding our expectations, regarding the timing of certain accomplishments, developments and milestones under our research and development programs. The actual timing of these events can vary significantly due to a number of factors, including, without limitation, the amount of time, effort and resources committed to our programs by us and any collaborators and the uncertainties inherent in the regulatory approval process. As a result, there can be no assurance that we or any collaborators will make regulatory submissions or receive regulatory approvals as planned or that we or any collaborators will be able to adhere to our current schedule for the achievement of key milestones under any of our programs. If we or any collaborators fail to achieve one or more of the milestones described above as planned, our business could be materially adversely affected and the price of our common stock could decline.

The coverage and reimbursement status of newly approved biopharmaceuticals is uncertain, and failure to obtain adequate coverage and adequate reimbursement of our product candidates could limit our ability to generate revenue.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. The commercial success of our product candidates, if approved, in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, and managed care organizations. Government and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new drugs and, as a result, they may not cover or provide adequate payment for our product candidates. These payors may conclude that our product candidates are less safe, less effective or less cost-effective

than existing or later introduced products, and third-party payors may not approve our product candidates for coverage and reimbursement or may cease providing coverage and reimbursement for these product candidates. Consolidation and integration among healthcare providers and health plans has increased their purchasing power and impacted reimbursement, and could continue to do so in the future. Because each country has one or more payment systems, obtaining reimbursement in the United States and internationally may take significant time and cause us to spend significant resources. The failure to obtain coverage and adequate reimbursement for our product candidates or healthcare cost containment initiatives that limit or deny reimbursement for our product candidates may significantly reduce any future product revenue.

In the United States and in other countries, there have been and we expect there will continue to be a number of legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business. International, federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Such government-adopted reform measures may adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payors. In addition, in some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. The continuing efforts of U.S. and other governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce healthcare costs may adversely affect our ability to set satisfactory prices for our products, to generate revenues, and to achieve and maintain profitability.

In some countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

Our development activities could be delayed or stopped for a number of reasons, many of which are outside our control, which could materially harm our financial results and the commercial prospects for our product candidates.

Each of our clinical trials requires the investment of substantial expense and time, and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes. We do not know whether our current clinical trials will be completed on schedule, or at all, and we cannot guarantee that our future planned clinical trials will begin on time, or at all. Clinical trials must be conducted in accordance with FDA or applicable foreign government guidelines and are subject to oversight by the FDA, foreign governmental agencies and independent institutional review boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current Good Manufacturing Practice, or cGMP, and other requirements in foreign countries, and may require large numbers of test patients. Our current and planned clinical trials could be substantially delayed or prevented by several factors, including:

- limited number of, and competition for, suitable sites to conduct our clinical trials;
- government or regulatory delays and changes in regulatory requirements, policy and guidelines;
- delay or failure to obtain sufficient supplies of the product candidate for, or other drugs used in, our clinical trials as a result of our suppliers' non-compliance with cGMP, or for other reasons;
- delay or failure to reach agreement on acceptable clinical trial agreement terms with prospective sites or investigators; and

· delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

· slower than expected rates of patient recruitment and enrollment;
· unforeseen safety issues;
· lack of efficacy evidenced during clinical trials, which risk may be heightened given the advanced state of disease and lack of response to prior therapies of patients in certain clinical trials;
· termination of our clinical trials by an IRB at one or more clinical trial sites;

- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols; and
- inability to monitor patients adequately during or after treatment or high patient dropout rates.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities or us. For example, in June 2017 we ended clinical development of EC1456 and stopped enrollment in our EC1456 phase 1b trial, as the assessment of trial data did not yield the level of clinical activity necessary to support continued advancement of EC1456. In December 2017, we stopped enrollment in our EC1456 ovarian cancer surgical trial. We cannot assure you that we will not terminate our current and future development programs.

Failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

Our product candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Common side effects of our product candidates include abdominal pain, vomiting, constipation, nausea, fatigue, loss of appetite, hematologic events and peripheral sensory neuropathy. Because our product candidates have been tested in relatively small patient populations and for limited durations to date, additional side effects may be observed as their development progresses.

177Lu-PSMA-617 is designed to target PSMA, a protein highly expressed on the surface of most prostate cancer cells but absent on most normal cells. However, the fact that PSMA is expressed on some normal cells may result in off-target toxicity due to the delivery of 177Lu, the cell-killing radioactive atom in 177Lu-PSMA-617, to those normal cells.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or discontinue clinical trials and could result in the denial, cancellation or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if one of our products receives marketing approval and we or others later identify undesirable side effects caused by that product:

- regulatory authorities may withdraw their approval of the product;

- we may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

· the product may be rendered less competitive and sales may decrease; or

· our reputation may suffer generally both among clinicians and patients.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating revenues from the sale of the product.

We may not obtain government regulatory approval to market our product candidates.

We may seek approval to market certain of our product candidates in both the United States and in non-U.S. jurisdictions. Prior to commercialization, each product candidate will be subject to an extensive and lengthy governmental regulatory approval process in the United States and in other countries. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive the approvals necessary to commercialize our product candidates in any market and we may withdraw applications for approval before acted upon by the regulatory authority.

We may not be able to obtain regulatory approval for any product candidates, or even if approval is obtained, the labeling for such products may place restrictions on their use that could materially negatively impact the marketability and profitability of the product subject to such restrictions. Satisfaction of these regulatory requirements, which includes satisfying regulatory authorities that the product is both safe and effective for its intended uses, typically takes several years or more depending upon the type, complexity, novelty and safety profile of the product and requires the expenditure of substantial resources. Uncertainty with respect to meeting the regulatory requirements governing our product candidates may result in excessive costs or extensive delays in the regulatory approval process, adding to the already lengthy review process.

Also, the approval procedure varies among countries and can involve additional testing and data review. The time and safety and efficacy data required to obtain foreign regulatory approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in any jurisdiction could materially harm our business.

We may require substantial additional funding which may not be available to us on acceptable terms, or at all.

As we work to advance product candidates through pre-clinical and clinical development, our future funding requirements will depend on many factors, including but not limited to:

- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates and conducting pre-clinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities if any of our product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any product candidates we successfully commercialize;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

- the timing, payments, receipts and amount of sales of, or royalties on, our product candidates, if any; and

- the costs we may incur and revenues we may generate in connection with in-licensing and out-licensing activities.

Until we can generate a sufficient amount of revenue to finance our cash requirements, which we may never do, and if we would require additional funding, we expect to finance future cash needs primarily through public or private equity or debt financings or other sources. We do not know whether additional funding will be available on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs, or enter into collaboration or other arrangements with other companies to provide such funding for one or more of such clinical trials or programs in exchange for our affording such partner commercialization or other rights to the product candidates that are the subject of such clinical trials or programs.

Furthermore, we may incur unexpected expenses, experience timing delays or encounter other circumstances that result in us needing additional funds sooner than planned. Also, we may seek additional capital due to favorable market conditions or other strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights.

We may seek the additional capital necessary to fund our operations through public or private equity or debt financings or other sources, such as strategic partnerships or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of the current stockholders will be diluted and the terms may include liquidation or other preferences that adversely affect their rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends, or which impose financial covenants on us that limit our operating flexibility to achieve our business objectives. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. In addition, we cannot assure you that additional funds will be available to us on favorable terms or at all.

If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address various types of cancer and other indications we treat or may treat in the future. We are currently developing cancer therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Also, certain of our product candidates may be clinically developed not as an initial first line therapy but as a therapy for patients whose tumors have developed resistance to first line chemotherapy, which limits its potential addressable market. Products we may develop in the future are also likely to face competition from other drugs and therapies.

Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large biopharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. Additional mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated by our competition. Competition may increase further as a result of advances in the commercial applicability of technologies currently being developed and a greater availability of capital investment in those fields. These companies may also have significantly greater research and marketing capabilities than we do. Some of the companies developing products which may compete with our product candidates include Adaptimmune Therapeutics PLC; Affimed N.V.; AstraZeneca PLC; Atara Biotherapeutics, Inc.; Atridia Pty LTD; Autolus Limited; Bayer AG; Bellicum Pharmaceuticals, Inc.; BioNTech AG; Bluebird Bio Inc.; Blue Earth Diagnostics Inc.; Cancer Targeted Technology LLC; Celgene Corporation; Cellectis S.A.; Celyad S.A.; Clarity Pharmaceuticals; Editas Medicine, Inc.; ESSA Pharma Inc.; Gilead Sciences, Inc.; GlaxoSmithKline plc; Immatics Biotechnologies GmbH; Immunocore Limited; Innocrin Pharmaceuticals Inc.; Intellia Therapeutics, Inc.; Intrexon Corporation; Isotope Technologies Munich AG; Janssen Biotech, Inc.; Johnson & Johnson; MedImmune, Inc.;

Merck & Co., Inc.; MorphoSys AG; Novartis AG; Progenics Pharmaceuticals, Inc.; Pfizer, Inc., Roche Holding AG; Suzhou Kintor Pharmaceuticals, Inc.; Takara Bio, Inc.; Telix Pharmaceuticals Limited; TRACON Pharmaceuticals, Inc.; Unum Therapeutics, Inc.; Zenith Pharmaceuticals Ltd; and Zymeworks Inc. In addition, many universities and private and public research institutes are active in cancer research, the results of which may result in direct competition with our product candidates. For example, the German Center of Cancer Research and University Medical Center Heidelberg, the owners of the patent rights to PSMA 617 (which have been exclusively licensed to ABX and, in turn, exclusively sublicensed to us under the License Agreement), may continue to engage in research relating to RLTs or other cancer therapies, which could result in competition for 177Lu-PSMA-617 or other product candidates that we advance from PSMA 617.

In certain instances, the drugs which will compete with our product candidates are widely available or established, existing standards of care. To compete effectively with these drugs, our product candidates will need to demonstrate advantages that lead to improved clinical safety or efficacy compared to these competitive products. We cannot assure you that we will be able to achieve competitive advantages versus alternative drugs or therapies. If our competitors' market products are more effective, safer or less expensive than our product candidates or reach the market sooner than our product candidates, we may not achieve commercial success.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to design and successfully execute appropriate clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the results of our clinical trials and the efficacy and safety of our product candidates;
- the speed at which we develop our product candidates;
- achieving and maintaining compliance with regulatory requirements applicable to our business;
- the timing and scope of regulatory approvals, including labeling;
- adequate levels of reimbursement under private and governmental health insurance plans, including Medicare;
- our ability to protect intellectual property rights related to our product candidates;
- our ability to commercialize and market any of our product candidates that may receive regulatory approval;
- our ability to have any partners manufacture and sell commercial quantities of any approved product candidates to the market;
- acceptance of our product candidates by physicians, other healthcare providers and patients; and
- the cost of treatment in relation to alternative therapies.

In addition, the biopharmaceutical industry is characterized by rapid technological change. Our future success will depend in large part on our ability to maintain a competitive position with respect to these technologies. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies. Also, because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success as a specialized scientific business depends on our continued ability to attract, retain and motivate highly qualified management and scientific and clinical personnel. The loss of the services of any of our senior management could delay or prevent the commercialization of our product candidates.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. In addition, the impact on employee morale experienced in connection with our workforce reduction in June 2017, in which we reduced our workforce by approximately 40%, could make it more difficult for us to retain current employees or to attract new employees when needed. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy.

If we evolve from a company primarily involved in clinical development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

If we are able to advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we may need to manage additional relationships with such third parties, as well as additional collaborators and suppliers.

Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management and other personnel. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. We may also begin to expand our capabilities or enter into contractual relationships during the later stage clinical trial or regulatory approval process, and then have to reduce our capabilities or terminate those relationships if the trials or approval processes are terminated.

Even if we are able to obtain regulatory approval of our products, we may be unable to successfully market and sell them unless we establish sales, marketing and distribution capabilities.

We currently have no sales or distribution capabilities and only limited marketing capabilities. If any of our product candidates receive regulatory approval, we intend to build a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. To the extent that we enter into co-promotion or other licensing arrangements, our product revenue is likely to be lower than if we directly marketed or sold our products and will depend in whole or in part upon the efforts of such third parties, which may not be successful and are generally not within our control. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

We rely on third parties to conduct clinical trials for our product candidates and plan to rely on third parties to conduct future clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, it may cause delays in commencing and completing clinical trials of our product candidates or we may be unable to obtain regulatory approval for or commercialize our product candidates.

Clinical trials must meet applicable FDA and foreign regulatory requirements. We do not have the ability to independently conduct phase 2 or phase 3 clinical trials for any of our product candidates. We rely on third parties, such as medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product candidates; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and other regulatory authorities require us to comply with regulations and standards, commonly referred to as Good Clinical Practices, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements.

We or the third parties we rely on may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials of our product candidates at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation.

The FDA and foreign regulatory agencies could also require additional clinical trials before or after granting marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market after obtaining marketing approval. Our failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval trials could result in the product being withdrawn from the market, either of which would have a material adverse effect on our business.

We rely on third parties to manufacture and supply our product candidates.

We do not currently own or operate manufacturing facilities for the clinical or commercial production of our product candidates. We lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. On July 5, 2018, we entered into the Supply Agreement with ITG for the clinical and commercial supply of no-carrier-added lutetium-177 for 177Lu-PSMA-617. Other than the Supply Agreement, we do not have any long-term supply arrangements with any third-party manufacturers and we obtain our raw materials on a purchase-order basis. We expect to continue to depend on third-party contract manufacturers for the manufacture of our product candidates and third-party shipping organizations and customs for timely delivery of our product candidates for the foreseeable future. If for some reason our contract manufacturers and shipping organizations cannot perform as agreed, we may be unable to replace them in a timely manner and the production and delivery of our product candidates would be interrupted, resulting in delays in clinical trials and additional costs. In addition, as a radioisotope, the shelf life of lutetium and 177Lu-PSMA-617 is limited, and therefore any disruption or delay in its delivery may result in product loss and the need to replace the affected product, which could delay our VISION trial or other clinical trials and could increase our costs.

We have no experience with managing the manufacturing of commercial quantities of any of our product candidates and scaling-up production to commercial quantities could take us significant time and result in significant costs. Switching manufacturers may be difficult because the number of potential manufacturers is limited and the FDA and other regulatory authorities must approve any replacement manufacturer prior to manufacturing our product candidates. Such approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our product candidates after receipt of regulatory approval to manufacture any of our product candidates.

To date, our product candidates have been manufactured in small quantities for pre-clinical studies and clinical trials by third-party manufacturers. If the FDA or other regulatory agencies approve any of our product candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of any approved product candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any approved product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation trials, which the regulatory agencies must review and approve. Additionally, any third-party manufacturer we retain to manufacture our product candidates on a commercial scale must pass a pre-approval inspection for conformance to the cGMP before we can obtain approval of our product candidates. If we are unable to successfully increase the manufacturing capacity for a product candidate in conformance with cGMP, the regulatory approval or commercial launch of such products may be delayed or there may be a shortage in supply.

Our product candidates require precise, high quality manufacturing. Failure by our contract manufacturers to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in testing or delivery, cost overruns, or other problems that could seriously harm our business. Contract manufacturers may encounter difficulties involving production yields, quality control and assurance.

These manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state and non-U.S. authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards; however, we do not have control over third-party manufacturers' compliance with these regulations and standards.

We are subject to risks associated with the availability of key raw materials, such as the radioisotopes used in the manufacture of our products.

The manufacture of our RLTs and companion imaging agents requires the use of raw materials which are subject, at times, to global supply chain risks that have the potential to delay or interrupt our work on the products incorporating those raw materials, compromise the products themselves and alter the costs of production. These risks include, in part: country of origin risk and the supplier's susceptibility to geopolitical and institutional threats; failure to make shipments and deliveries in an accurate, consistent and timely manner, including as a result of disruptions such as natural threats; lack of physical security of and at the supplier's location(s); insufficient internal processes and controls of the supplier during the manufacturing process; and inadequate compliance with social and environmental responsibilities of the supplier that include, but are not limited to, product safety regulations, labor relations, and waste product generation and removal. For example, any limitation on our ability to source adequate and timely supply of lutetium-177 for 177Lu-PSMA-617 could prevent us from gathering sufficient data in clinical trials, result in delays in the regulatory approval process or to the extent that we obtain regulatory approval for marketing for this product candidate, a limited supply may prevent us from launching and/or meeting commercial demands for the product in desired markets. Supply constraints for lutetium-177 could also materially increase the manufacturing costs of 177Lu-PSMA-617, which would increase the cost of our clinical trials and reduce the commercial potential of the product candidate.

In addition, we plan to use etarfolatide that employs Tc-99m in our development of imaging capabilities and there have been historical periods in which global supply was not sufficient to satisfy worldwide demand for use in various nuclear medicine diagnostics utilized by healthcare providers. If we are not able to obtain sufficient quantities of Tc-99m for use in etarfolatide, we may not be able to gather sufficient data on etarfolatide to use in future clinical trials or to possibly seek the approval of etarfolatide. In addition, to the extent the approval of our product candidates depends on the screening and monitoring of the patient population with a companion imaging agent such as etarfolatide in our clinical trials, we would experience a corresponding delay in approval and commercialization of these product candidates if we are not able to obtain sufficient Tc-99m.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.

The use of any of our product candidates in clinical trials, and the sale of any approved products, may expose us to product liability claims. We currently maintain product liability insurance coverage in an amount which we believe is adequate for our clinical trials currently in progress and those recently completed. We monitor the amount of coverage

we maintain as the size and design of our clinical trials evolve and intend to adjust the amount of coverage we maintain accordingly. However, we cannot assure you that such insurance coverage will fully protect us against some or all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

Each of our product candidates will remain subject to ongoing regulatory review even if it receives marketing approval. If we or any collaborators and contractors fail to comply with continuing regulations, we or they may be subject to enforcement action that could adversely affect us.

If any of our product candidates become approved products, they will continue to be subject to pervasive regulation by the FDA and other regulatory authorities. We and any collaborators and contractors will continue to be subject to regulatory requirements governing among other things the manufacture, packaging, sale, promotion, adverse event reporting, storage and recordkeeping of our approved products. Although we have not received any notice that we are the subject of any regulatory enforcement action, it is possible that we may be in the future and that could have a material adverse effect on our business. We may be slow to adapt, or may never adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements. If we or any collaborators or contractors fail to comply with the requirements of the FDA and other applicable governmental or regulatory authorities or previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we or the collaborator or contractor could be subject to administrative or judicially imposed sanctions, including: fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our activities involve the controlled storage, use, and disposal of hazardous materials, including corrosive, explosive and flammable chemicals, biologic waste and various radioactive compounds. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. Although we believe that our safety procedures for the handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials.

In the event of an accident, state or federal authorities may curtail our use of these materials, and we could be liable for any civil damages, which may exceed our financial resources and may seriously harm our business. We currently maintain insurance covering hazardous waste clean-up costs in an amount we believe to be sufficient for typical risks regarding our handling of these materials, however, this amount of coverage may not be sufficient to cover extraordinary or unanticipated events. Additionally, an accident could damage, or force us to temporarily shut down, our operations.

Risks Related to Intellectual Property

We may be at risk for cyber attacks or other security breaches that could compromise our intellectual property, trade secrets or other sensitive business information and expose us to liability, which would cause our business and reputation to suffer.

Cyber attacks or security breaches could compromise confidential, business critical information, cause a disruption in our operations, harm our reputation or increase our stock trading risk. We have attractive information assets, including intellectual property, trade secrets and other sensitive, business critical information, including personally identifiable information of our employees. Our employees, some of whom have access to such information, frequently receive "phishing" emails intended to trick recipients into surrendering their user names and passwords. Phishing is a fraud method in which the perpetrator sends out legitimate-looking emails in an attempt to gather personal, business, financial or other information from recipients. To date, we have found no evidence of unauthorized access to our employees' accounts, but cannot preclude the possibility that sensitive information has been accessed, publicly disclosed, lost or stolen.

We have cybersecurity technologies, processes and practices that are designed to protect networks, computers, programs and data from attack, damage or unauthorized access, but we cannot assure you that they will be effective or will work as designed. Our cybersecurity is continuously reviewed, maintained and upgraded in response to possible security breach incidents. Notwithstanding these measures, a cyber attack could compromise our networks and data centers and/or result in access, disclosure, or other loss of information, which could result in legal claims or proceedings, investigations, potential liabilities under laws that protect the privacy of personal information, delays and impediments to our discovery and development efforts, including our clinical trials, damage to our reputation and a negative impact on our financial results.

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. The existing patent rights that we own or license, and any future patents rights, may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. We cannot be certain that patent applications will be approved or that any patents issued will adequately protect our or our licensors' intellectual property. With respect to PSMA 617 and EC17/CAR T-cell therapies, for example, other than in the PSMA-617 family for Australia, Columbia, New Zealand, and Singapore, patents have yet to issue and the patents may not issue at all, or if they do issue, they may be challenged. In addition, we often do not ultimately control the patent prosecution of subject matter that we license from others, including those licensed from Purdue Research Foundation, a non-profit organization which manages the intellectual property of Purdue University. In addition, we have licensed intellectual property from other third parties, such as ABX, where we were not involved in preparing, drafting or filing the patent applications. Accordingly, we are unable to exercise the same degree of control over this intellectual property as we would over our own and would need to involve such third parties in legal proceedings to enforce these intellectual property rights. Moreover, the patent positions of biopharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are often evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;

- we or our licensors were the first to file patent applications for these inventions;

- any of our product candidates will be Orange Book eligible;

- others will independently develop similar or alternative technologies or duplicate any of our technologies;

- any of our or our licensors' pending patent applications will result in issued patents;

- any of our or our licensors' patents will be valid or enforceable;

- any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, or will be challenged by third parties;

- we will develop additional proprietary technologies that are patentable;

- the U.S. government will exercise any of its statutory rights to our intellectual property that was developed with government funding; or

- our business may infringe the patents or other proprietary rights of others.

The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patent and the financial ability of us or a third party to enforce the patent and other intellectual property. Our ability to maintain and solidify our proprietary position for our products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely upon unpatented proprietary know-how and continuing technological innovation and other trade secrets in connection with the development of our technologies and product candidates. While it is our policy to enter into agreements imposing confidentiality obligations upon our employees and third parties, including our collaboration partners, to protect our intellectual property, these confidentiality obligations may be breached, may not provide meaningful protection for our trade secrets or proprietary know-how, or adequate remedies may not be available in the event of an unauthorized access, use or disclosure of our trade secrets and know-how. In addition, others could obtain knowledge of our trade secrets through independent development or other access by legal means. Further, non-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets.

The failure of patent rights or confidentiality agreements to protect our processes, technology, trade secrets or proprietary know-how or the failure of adequate legal remedies for related actions could have a material adverse effect on our business, results of operations, financial condition and liquidity.

The intellectual property protection for our product candidates is dependent on third parties.

While we do have the right and responsibility under the License Agreement to control the prosecution and maintenance of the patent rights covering PSMA 617, we are subject to certain consent and cooperation obligations to ABX and/or the owners of the patent rights. With respect to patent applications relating to our product candidates that incorporate patents licensed from Purdue Research Foundation, the right and obligation to prosecute and maintain the patents and patent applications covered by these license agreements are generally retained by Purdue Research Foundation. Generally, we do not have the right to prosecute and maintain such patents in our territories, unless Purdue Research Foundation elects not to file, prosecute or maintain any or all of such patents, however, our most recent master license agreement for future potential technology provides us lead prosecution responsibility. We would need to determine, with our other potential partners, who would be responsible for the prosecution of patents relating to any joint inventions. If any of our licensing partners who maintain such rights fail to appropriately prosecute and maintain patent protection for any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

If we breach any of the agreements under which we license commercialization rights to our product candidates or technology from third parties, we could lose license rights that are important to our business.

We license the use, development and commercialization rights for some of our product candidates, and we expect to enter into similar licenses in the future. For example, we licensed exclusive worldwide rights from ABX and Purdue Research Foundation, pursuant to license agreements, which enables us to use PSMA-617 and adaptor-controlled EC17/CAR T-cell therapies, respectively, in the treatment of cancer. Under these licenses, we are subject to development and commercialization obligations, diligence obligations, sublicense revenue sharing requirements, royalty payments, and other obligations. If we fail to comply with any of these obligations or otherwise breach a license agreement or any other current or future licenses, our licensing partners may have the right to terminate the license in whole or in part or to terminate the exclusive nature of the license. In addition, if ABX fails to comply with its obligations under its license agreement with the owners of the patent rights covering PSMA-617, our rights under the License Agreement with ABX could be materially impaired. The loss of any current or future licenses or the exclusivity rights provided therein would materially harm our financial condition and operating results.

The patent protection for our product candidates may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our product candidates have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential market territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review. However, we cannot be certain that such an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extension period will be. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain the exclusive time period. If we are unable to obtain patent term extension/restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of patents.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where there is no patent protection for our product candidates to develop their own products and further, may export otherwise infringing products to territories where there is patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have rights to any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult to stop the infringement of the patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

If we are sued for infringing intellectual property rights of third parties, litigation will be costly and time-consuming and could prevent us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our not infringing the patents and proprietary rights of other parties and not breaching any collaboration or other agreements we have entered into with regard to our technologies and product

candidates. Numerous third-party U.S. and non-U.S. issued patents and pending applications exist in the areas of targeted therapy and targeted diagnostics, including RLTs, CAR T-cell therapies, cytotoxic agents and other active compounds and formulations comprising such compounds.

Because patent applications can take several years to issue, if they are issued at all, there may currently be pending applications, unknown to us, that may result in issued patents that cover our technologies or product candidates. It is uncertain whether the issuance of any third-party patent would require us to alter our products or processes, obtain licenses or cease activities related to the development or commercialization of our product candidates. If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we may need to obtain a license from the owner, enter into litigation to challenge the validity of the patents or incur the risk of litigation in the event that the owner asserts that any of our product candidates infringe its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our products may have a material adverse impact on us.

There is a substantial amount of litigation involving intellectual property in the biopharmaceutical industry generally. If a third party asserts that our products or technologies infringe its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from our business;

- substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a third party's patent or other proprietary rights;

- a court prohibiting us from selling or licensing our technologies or our product candidates unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or lump sum payments or grant cross-licenses to our patents or other proprietary rights to obtain that license; and

- redesigning our products so they do not infringe, which may not be possible or may require substantial monetary expenditure and time.

Although we are not currently a party to any legal proceedings relating to our intellectual property, in the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert these claims against us or against the current or future licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit, whether they are resolved in favor of or against us or our licensors, we may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, if at all, which could seriously harm our business or financial condition.

One or more third-party patents or patent applications may conflict with patent applications to which we have rights. Any such conflict may substantially reduce the coverage of any rights that may issue from the patent applications to which we have rights. If third parties file patent applications in technologies that also claim technology to which we have rights, we may have to participate in interference proceedings with the U.S. Patent and Trademark Office, or USPTO, or non-U.S. patent regulatory authorities, as applicable, to determine priority of invention.

We may become involved in lawsuits to enforce patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe the patents or other intellectual property rights related to our product candidates. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. To the extent such claims relate to patent rights held by our licensors, they would have to file such an infringement lawsuit since we do not have the independent right to enforce those third parties' intellectual property. In

addition, in an infringement proceeding, a court may decide that a patent is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of the patents at risk of being invalidated or interpreted narrowly and could put patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future licensors or collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors or collaborators, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Risks Related to Ownership of Our Common Stock

The price of our common stock has been volatile and our shares may suffer a decline in value.

Since becoming a public company in February 2011, we have experienced volatility in the trading price of our common stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to, the risk factors identified above as well as:

- results from, supplemental analyses of and any delays in, our current or planned clinical trials;
- announcements of approval or non-approval by any regulatory authorities of any of our product candidates, or delays in any regulatory authority review processes;
- other regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product candidates;
- failure or discontinuation of any of our research or clinical trial programs;
- withdrawal of regulatory approval applications;
- delays in the commercialization of our product candidates;
- our ability to effectively partner with collaborators to develop or sell our products;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;

- actual and anticipated fluctuations in our quarterly operating results;

- developments or disputes concerning our intellectual property or other proprietary rights;

- introduction of technological innovations or new products by us or our competitors;

- issues in supply or manufacturing of our product candidates;

- market acceptance of our product candidates;

- deviations in our operating results from the estimates of securities analysts;

- coverage and reimbursement policies of governments and other third-party payors;

- sales of our common stock by our officers, directors or significant stockholders;

- price and volume fluctuations in the overall stock market from time to time;

- general economic conditions and trends;

- major catastrophic events;

- our ability to expand our operations, domestically and internationally, and the amount and timing of expenditures related to this expansion; and

- additions or departures of key personnel.

In addition, the stock markets in general, and the markets for biopharmaceutical, pharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that has been often unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In the past, when the market price of a stock has been volatile, holders of that stock have sometimes instituted securities class action and other litigation against the issuer. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the attention of our management would be diverted from the operation of our business, which could result in the delays of our clinical trials or other efforts.

*Sales of substantial amounts of our shares could adversely affect the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur, could cause the market price of our common stock to decline. These sales could also make it more difficult for us to raise capital by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

As of September 30, 2018, there were 81,323,300 shares of our common stock outstanding. All of the outstanding shares are freely transferable without restriction under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates” as that term is used in Rule 144 promulgated under the Securities Act or unless issued in an unregistered offering. Such shares may be sold in the public market pursuant to Rule 144, another exemption from registration or an effective registration statement under the Securities Act.

We do not intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

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Provisions in our certificate of incorporation and bylaws and under Delaware law might discourage, delay or prevent a change of control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our certificate of incorporation and bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change of control of our company or changes in our management that our stockholders may deem advantageous. These provisions include:

- establishing a classified board so that not all members of our Board of Directors are elected at one time;
- authorizing "blank check" preferred stock that our Board of Directors could issue to increase the number of outstanding shares to discourage a takeover attempt;
- eliminating the ability of stockholders to call a special stockholder meeting;
- eliminating the ability of stockholders to act by written consent;
- being subject to provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers;
- providing that our Board of Directors is expressly authorized to make, alter or repeal our bylaws; and
- establishing advance notice requirements for nominations for elections to our Board of Directors or for proposing other matters that can be acted upon by stockholders at stockholder meetings.

If securities or industry analysts issue an adverse opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us adversely change their recommendation regarding our common stock, or provide more favorable relative recommendations about our competitors, the trading price of our common stock could decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price of our common stock or trading volume to decline.

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on the Nasdaq Global Market.

Market conditions may result in volatility in the level of, and fluctuations in, market prices of stocks generally and, in turn, our common stock and sales of substantial amounts of our common stock in the market, in each case being unrelated or disproportionate to changes in our operating performance. A weak global economy could also contribute to extreme volatility of the markets, which may have an effect on the market price of our common stock.

If we fail to maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

We are subject to the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, which requires management to assess and report annually on the effectiveness of internal control over financial reporting and identify any material weaknesses in internal control over financial reporting, and our independent registered public accounting firm to issue an attestation report as to the effectiveness of internal control over financial reporting.

If we identify one or more material weaknesses in our internal control over financial reporting, or if we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us with an attestation report on the effectiveness of internal control over financial reporting, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions.

Our ability to use net operating losses to offset future taxable income is subject to certain limitations.

Under Section 382 of the U.S. Internal Revenue Code, or Code, a corporation that experiences a more-than 50 percent ownership change over a three-year testing period is subject to limitations on its ability to utilize its pre-change net operating losses to offset future taxable income. We experienced such an ownership change in August 2011. As a result, the future use of our net operating losses and credit equivalents, after giving effect to net unrealized built-in gains, was previously limited, but the limitations associated with the change in ownership in August 2011 ended as of December 31, 2017. All amounts are available for use if we generate future taxable income prior to expiration of the net operating losses, which will begin in 2021. Furthermore, the utilization of the net operating loss carryforwards could be limited beyond our generation of taxable income if an additional change in the underlying ownership of our common stock has occurred subsequent to August 2011, resulting in a limitation on the amounts that could be utilized in any given period under Section 382 of the Code. At December 31, 2017, we recorded a full valuation allowance against our deferred tax assets of approximately $95.9 million, as we believe it is more likely than not that the deferred tax assets will not be fully realized.

*Our Amended and Restated Bylaws designate certain Delaware courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

On October 17, 2018, our Board of Directors approved an amendment, or the Bylaws Amendment, to our Amended and Restated Bylaws, or the Bylaws, effective as of such date, in order to add an exclusive forum provision for the adjudication of certain disputes. The Bylaws Amendment, set forth in a new Article XI of the Bylaws, provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of our company, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of ours to our company or our stockholders, (iii) any action or proceeding asserting a claim arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the laws of the State of Delaware (including the General Corporation Law of the State of Delaware, or the DGCL), our Amended and Restated Certificate of Incorporation or the Bylaws (as each may be amended from time to time), (iv) any action or proceeding as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (v) any action or proceeding asserting a claim governed by the internal affairs doctrine.

Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our common stock will be deemed to have notice of and consented to the provisions of this exclusive forum provision and to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware.

The choice of forum provision in the Bylaws Amendment may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find any provision of the Bylaws Amendment inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Securities

None.

Item 6. Exhibits

See the Exhibit Index immediately preceding the signature page to this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of October 17, 2018, by and among Novartis AG, Edinburgh Merger Corporation and Endocyte, Inc. (incorporated by reference from Exhibit 2.1 to the Current Report on Form 8-K filed October 18, 2018)
3.1	Amended and Restated Certificate of Incorporation of Endocyte, Inc. (incorporated by reference from Exhibit 3.1 to the Annual Report on Form 10-K for the year ended December 31, 2010 filed March 18, 2011)
3.2	Amended and Restated Bylaws of Endocyte, Inc., effective October 17, 2018 (incorporated by reference from Exhibit 3.1 to the Current Report on Form 8-K filed October 18, 2018)
10.1*	Global Supply Agreement, dated as of July 5, 2018, between Endocyte, Inc. and ITG Isotope Technologies Garching GmbH (incorporated by reference from Exhibit 10.1 to the Current Report on Form 8-K filed July 11, 2018)
10.2	Form of 2010 Equity Incentive Plan Time-Based Restricted Stock Unit Award Agreement (Employees) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.4 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
10.3	Form of 2010 Equity Incentive Plan Stock Option Award Agreement (Employees) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.5 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
10.4	Form of 2010 Equity Incentive Plan Time-Based Restricted Stock Unit Award Agreement (Directors – Initial Grants) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.6 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
10.5	Form of 2010 Equity Incentive Plan Stock Option Award Agreement (Directors – Initial Grants) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.7 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
10.6	Form of 2010 Equity Incentive Plan Time-Based Restricted Stock Unit Award Agreement (Directors – Annual Grants) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.8 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
10.7	Form of 2010 Equity Incentive Plan Stock Option Award Agreement (Directors – Annual Grants) (for use after July 18, 2018) (incorporated by reference from Exhibit 10.9 to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 1, 2018)
31.1	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934 of the Chief Executive Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934 of the Chief Financial Officer, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following materials from Endocyte, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in Extensible Business Reporting Language (XBRL), includes: (i) Condensed Balance Sheets at December 31, 2017 and September 30, 2018, (ii) Condensed Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2017 and 2018, (iii) Condensed Statement of Stockholders' Equity (Deficit) for the nine months ended September 30,

2018, (iv) Condensed Statements of Cash Flows for the nine months ended September 30, 2017 and 2018 and (v) Notes to Condensed Financial Statements.

*The Securities and Exchange Commission has granted our request that certain provisions of this exhibit be treated as confidential. Such material has been redacted from the exhibit as filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENDOCYTE, INC.

Date: November 8, 2018 By: /s/ Michael A. Sherman
Michael A. Sherman
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2018 By: /s/ Michael T. Andriole
Michael T. Andriole
Chief Financial Officer
(Principal Financial Officer)

Date: November 8, 2018 By: /s/ Beth A. Taylor
Beth A. Taylor
Vice President of Finance and Chief Accounting Officer
(Principal Accounting Officer)